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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91194218
Party	Plaintiff Illumina, Inc.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL APPEAL BOARD

ILLUMINA, INC.,	) Opposition No. 91194218
	) (parent)Ser. No.77/768176
Opposer/Petitioner,	)
	) Opposition No. 91194219
vs.	) Ser No. 77/775316
	)
MERIDIAN BIOSCIENCE, INC.,	) Cancellation No.
	) 92053479 Reg No. 3887164
Applicant/Registrant.	) Cancellation No.
	) 92053479 Reg No. 386801

CONFIDENTIAL - UNDER THE PROTECTIVE ORDER

Deposition of Vecheslav A. Elagin, Ph.D., Ph.D., MBA, a witness herein, called by the Opposer/Petitioner, for oral examination, pursuant pursuant to the Federal Rules of Civil Procedure taken before George J. Staiduhar, Notary Public in and for the State of Ohio, pursuant to Notice at the offices of Keating Muething & Klekamp, PLL One East 4th Street, Suite 1400, Cincinnati, Ohio 45202 on Tuesday, March 10th, 2015, at 9:00 a.m.

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I N D E X

WITNESS: Vechelslav A. Elagin, Ph.D., MBA

E X H I B I T S

VECHESLAV A. ELAGIN, Ph.D., MBA

of lawful age, being first duly sworn, as hereinafter certified, was examined and testified as follows:

MR. HORNE: Okay. I guess we should give our appearances. I am Brian Horne from Knobbe Martens for Illumina. With me is Wil Moon from Illumina.

MR. HANKINSON: Thomas Hankinson representing Meridian and also Michael Hurst representing Meridian.

EXAMINATION ON BEHALF OF COUNSEL FOR OPPOSER/PETITIONER

BY MR. HORNE:

Q. State your name for the record, please.

A. Vecheslav Elagin.

Q. And who are you working for?

A. Meridian Bioscience.

Q. You pronounce your name Elagin?

A. Elagin.

Q. Mr. Elagin, have you been deposed before?

A. Yes, once.

Q. When was that?

A. That was in 2005.
Q. What was the nature of that proceeding?
A. It was patent infringement case.
Q. Who were the parties in that case?
A. Third Wave Technologies and EraGen.
Q. You were working for Third Wave at the time?
A. Yes.
Q. What was the nature of the technology at issue at time?
A. Real-time PCR.
Q. What was your role in the case?
A. I was vice president of research for Third Wave Technologies.
Q. Do you remember why you were deposed?
A. We were running some experiments to prove that EraGen infringed our patent, and I was obviously supervising all the experiments and all data.
Q. So since it has been ten years since you have been deposed, I want to go over the ground rules.

First, you understand that your

testimony this morning is sworn testimony under oath as if you were testifying in Court.

A. Yes.

Q. Deposition works, I will ask you a series of questions, and you are to answer those questions to the best of your ability. If for some reason you don't understand a question, will you please ask for clarification?

A. Okay.

Q. If you don't ask for clarification, we are going to proceed with the assumption that you understood the question.

A. Yes.

Q. Do you understand that?

A. Yes.

Q. Okay. We will be going for a better part of the day. I will try to take breaks every hour to hour-and-a-half. In if you need a break for some reason to stretch your legs, take a restroom break, get a glass of water, please let me know.

A. Absolutely.

Q. I will do my best to accommodate you. I only ask that you don't take a break if there is a question pending. Do you understand that?
A. Okay.
Q. Okay. Few other things, we have a court reporter typing down my questions and your answers. So it is important to give verbal answers to the questions. Shakes of the head, nods of the head, things like uh-uh, uh-uh don't transcribe very well.
A. Understood.
Q. It is important to let me finish my question and not talk over me. I will try to give you the same courtesy. Do you understand that?
A. Yes.
Q. Oftentimes I will be asking a question. You will kind of know what the question is going to be, and you will have the instinct to jump in and answer the question before I finish, but because it is a little bit more of a formal process, we need to get a full record of what the question was before we get the answer.

So please do your best to let me get the question out fully before you answer. Can you do that?

A. Okay.

Q. Counsel may object from time to time to my questions. Unless he specifically instructs you not to answer one of the questions, you still have to answer the question. Do you understand that?

A. Yes.

Q. Is there any reason you can't give true and accurate testimony today?

A. I will give my true and accurate testimony today.

Q. Good. Did you do anything to prepare for your deposition?

A. Yes, of course.

Q. What did you do?

A. I read the Illumina trademarks, the trademarks from Meridian Bioscience. I read the testimony deposition from two witnesses from your side, and it was a while since I did my testimony --

my declaration as well.
Q. Did you meet with anybody to prepare for your deposition this morning?
A. Yes.
Q. Who did you meet with?
A. With my counsel.
Q. Mr. Hankinson?
A. Yes.
Q. And when did you meet with Mr. Hankinson?
A. Friday of last week.
Q. For how long?
A. I guess for five hours.
Q. Was anybody else at the meeting with Mr. Hankinson?
A. Yes. Mr. Hurst and Ken Kozak, who you met yesterday.
Q. Other than the meeting on Friday, did you meet with anybody else, have any other discussions with anybody to prepare for today's deposition?
A. No.
Q. I want to go through a little bit of your work

history.

'92 to '96, according to your declaration, you were a staff scientist. Is that accurate?

A. Yes.

Q. What did you do as a staff scientist?

A. So we are talking about staff scientist where, '92 to '96?

Q. '92 to '96 it was at --

A. I was in Moscow Institute of General Genetics and then Moscow Institute of Molecular Biology.

Q. Could you generally describe what your responsibilities were there?

A. I was responsible for conducting research studies on genetics and chromosomal rearrangements, and I had two Ph.D. students working for me.

Q. And I am bad as well. It is helpful to talk slow if you can. I am a notoriously fast talker and get a lot of scowls from court reporters, so if we will both try to talk a little slower, it will probably help.

A. Yeah.
Q. After that you went to be Notre Dame?
A. Yes, correct.
Q. And you were a research assistant professor at Notre Dame?
A. I started as a post doc, and six months later I received my NIH grant, RH 01, and I was promoted to research assistant professor, yes.
Q. And what did you do as a research assistant professor at Notre Dame?
A. I conducted research on genetic differences for neurobiology, and I did teaching of one class for students.
Q. What class did you teach?
A. Microbiology.
Q. Then in 2000, you went to Visible Genetics?
A. This is correct.
Q. What did you do at Visible Genetics?
A. I was group leader to develop two products for Visible Genetics, which are human hepatitis C virus, genotyping, and human hepatitis B, drug resistant test. They both were on the company

technology, which was a standard sequencing assays.

I also worked as a manager of CLIA certified laboratory because we did clinical trials for pharmaceutical companies like Rausch, like Galaxy, like Abbott. They were conducting clinical trials for different drugs, so I would say antiviral drugs.

Q. Did the CLIA lab at Visible Genetics -- and by the way, CLIA is C-L-I-A?

A. Yes. All capitals.

Q. Sorry. What does that stand for?

A. CLIA in 1982, it was amendment by FDA of Clinical Laboratory Improvement Amendment Act, and currently, all laboratories will work under those regulations, and regulations are evolving, but it started as a certification long time as Clinical Laboratory Improvement Amendment Act.

Q. Can you explain what a CLIA certified lab is? Can you tell us what it does?

A. First of all, for CLIA certification, you have to have right personnel and right laboratory

head that has all required education, certification to run those laboratories. Typical head of laboratory would have some credentials from different institutions like medical pathology credentials or human genetic credentials.

It is typically a person who has an M.D., Ph.D., so I was manager, but I reported to the head of this CLIA laboratory as a person who has all these credentials and who has this -- those certifications.

On top of this, you have to have right personnel with the right education and background that needs to be documented in terms of running all these laboratories because you are reporting clinical results. So you have to have certain regulations, like what's your quality control procedures are, what's your cleaning procedures are for laboratories, what's your testing reports, procedures, and all needs to be documented and needs to be certified.

So there are several

certifications, and they could be done by different states like the State of New York certification or State of Georgia certification, and you have to conduct and go through all audits at this point.

Q. You said you worked on human hepatitis?

A. C and hepatitis B.

Q. Hepatitis B?

A. And B and C. There are two hepatitis.

Q. What can you describe what that product was, or was it a product?

A. Absolutely. Both were based on sequencing technology, which is all Sanger, S-a-n-g-e-r, technology. It is essentially purifying your RNA. You are conducting or converting this to CDNA, and then you are doing sequence, and software will analyze mutations that will either call it for this particular genotype of hepatitis C, or it will call for point mutations for hepatitis B, because some of those mutations are associated with drug resistance.

Q. Was that product, the hepatitis product at

Visible Genetics, was that FDA approved?
A. Those two products were not FDA approved.
Q. What were they used for?
A. They were used to take and detect either drug resistance for hepatitis B or what's genotype for hepatitis C. We had a different problem, which was PMA approved, and I was working on the -- supporting this product, which was HIV drug resistant test and Visible Genetics had this product the first PMA approval.
Q. Could you explain the -- I understand the hepatitis product was used to detect drug resistance. Who was using this product to detect drug resistance?
A. Virology laboratories in the United States, customers like Mayo Clinics.
Q. The CLIA lab at Visible Genetics, that was used for clinical trials for drugs?
A. Yes.
Q. And it was -- what else was it used for?
A. That's it. We were not competing with our customers so only big pharmaceutical companies

were competing with us.
Q. Who were your customers for Visible Genetics.
A. For products?
MR. HANKINSON: Objection to form.
Q. Yeah, yes.
A. Customers for products?
Q. Yes.
A. Virology laboratories in the United States. I gave you an example already, Mayo Clinic, for example.
Q. And did Visible Genetics' customers use the hepatitis products for diagnoses purposes?
MR. HANKINSON: Objection to form.
THE WITNESS: What does that mean? I'm sorry. I forgot. If you don't mind. (Directed to Mr. Hankinson,)
MR. HANKINSON: When I object, unless I tell you not to answer, you should go ahead and answer the question if you remember it. If you need it repeated, then you can have it repeated, just ask him.

But I will be objecting prior to some of your answers. I am objecting to the question, and then you go ahead and answer if you can.

A. Okay. They were working and reporting those results, yes, because we sold the product in the ASR format.

Q. To whom would the -- would Visible customers report the results that you just described?

A. I'm sorry.

Q. You said they would work and report results. Who were they reporting the results to?

A. They would report the results to treating clinician.

Q. Treating clinician?

A. Yes, our customer.

Q. If the Visible Genetics product was not FDA approved, how were your customers able to use that product --

A. Analyte specific reagents, that's how we were working.

Q. What does that mean?

A. Analyte specific reagents.
Q. Maybe that answered my question; maybe it didn't. Let me ask the question again so we are on the same page. If the Visible Genetics products were not FDA approved or FDA cleared --
A. Not correct. One product was FDA approved. Two products were not FDA approved.
Q. Okay. What product was FDA approved?
A. HIV product.
Q. And hepatitis products were not FDA approved?
A. They were not FDA approved.
Q. Were the hepatitis products, were they the same customers of the virology departments?
A. Yes.
Q. How would Visible Genetics' customers use the hepatitis products?
A. They will do same procedure as products for HIV, and they will diagnose patients.
Q. How were the customers, how were Visible Genetics' customers able to use the hepatitis products, which were not FDA approved, in order to diagnose patients?

MR. HANKINSON: Objection to form.

A. So we have an HIV FDA approved product. Okay? I just will go slow through some of the steps. That product was designed and developed on a special sequencing machine, which was FDA approved and actually cleared through PMA.

So hepatitis products were designed to use on the same FDA cleared machine with different reagents that we sold, analyte specific reagents in a different software, and customer obviously did their own validations because reagents were analyzed specifically, but at Visible Genetics, the reagent went through the same quality control and manufacturing process as FDA cleared product.

Q. After Visible Genetics, you went to Third Wave Technologies?

A. Yes.

Q. Why did you leave Visible Genetics?

A. Visible Genetics was acquired by Bayer Nucleic Acid Diagnostic Division in 2002.

Q. What was the business of Third Wave

Technologies?

A. Third Wave Technologies had reagents for research use only, for diagnosing of single nucleotide polymorphisms for humans, and it had also created diagnostic division.

Q. What type of products did Third Wave make in the diagnostic division?

A. Factor V and Factor II, cystic fibrosis, hepatitis C, genotyping, human papillomavirus.

Q. Were all of those products FDA cleared?

A. No.

Q. Which ones were? Were any of them FDA cleared?

A. Human papillomavirus was PMA cleared, Factor V, Factor II were cleared as well. Cystic fibrosis on microfluidics card cleared as well. Hepatitis C is not, and it is discontinued at this point.

Q. Did Third Wave ever sell its hepatitis C product?

A. Yes.

Q. To whom?

A. To virology laboratories as an ASR format.

Q. I apologize if I already asked you this, but if I did, I don't remember. What does ASR format mean?

A. Analyte specific reagents, and there is a special quality control and manufacturing procedures that you have to follow in order to manufacture and distribute those products.

Q. Do you know how the virology labs used Third Wave's hepatitis C products?

A. Yes. They were using those products to diagnose hepatitis C and report results to physician.

Q. If the hepatitis product was not FDA cleared how were the virology labs able to use that product in order to diagnose patients?

MR. HANKINSON: Objection to form.

A. For laboratory to use analyte specific reagents, they have to validate those reagents in their own laboratory and create protocol and create work flow, and I forgot to mention those laboratories must be CLIA certified in order to do that.

Q. Have you heard of the term "lab developed

test"?

A. Yes.

Q. And is what you are just describing, would you consider that to be a lab developed test?

A. No.

Q. What's the difference between what you were just describing and a lab developed test?

A. Analyte specific reagents are for use under strict manufacturing and quality control rules. Laboratory developed tests, it is what the laboratory developed by themselves from research, using only reagents that have no quality controls at this point, and it is the responsibility of the laboratory to do all incoming controls of quality materials, concentrations, and so on and so forth; so laboratory developed tests, next level of regulation and complexity, analyte specific reagents; next level is CLIA tests and there is three different requirements for all of them.

Q. Thank you. That was helpful.

MR. HANKINSON: Let the record reflect that during a prior answer, as the levels were being described, Mr. Elagin's hand started in a low position flat out and then progressed to two higher positions still flat out.

Q. The virology labs that purchased the hep C products from Third Wave, which were not FDA cleared, did those virology labs also purchase FDA cleared IVD products?

MR. HANKINSON: Objection to form. Compound.

A. From Third Wave or other companies? You said products. Describe what you --

Q. I will start with Third Wave. Thanks for the clarification?

MR. HANKINSON: Same objection.

A. Yes. They were purchasing other products as well.

Q. Other FDA --

A. Other FDA cleared virology products from Third Wave and from other companies.

Q. Thank you. What specifically were your responsibilities at Third Wave?
A. I was vice president of research and development.
Q. What were your responsibilities as vice president of research and development?
A. Develop new products, communicate with customers, find new product ideas.
Q. During your time at Third Wave, did you ever come across Illumina?
A. Yes.
Q. And in what context?
A. In research markets, we and Illumina were playing the same field of high throughput human single nucleotide polymorphism detection in research market. I do not know if you might remember on the news 2005-2006 this research for human genome project.
Q. I heard of that?
A. That's what we were working on.
Q. When you say "we" do you mean Third Wave or Third Wave and Illumina?

A. Third Wave and Illumina.
Q. What types of products did Third Wave make for the research market?
A. Products for human genome polymorphism detection.
Q. At Third Wave, was there ever a crossover between the customers for Third Wave's research products and the customers for Third Wave's FDA cleared products?
MR. HANKINSON: Objection to form.
A. No, never.
Q. After Third Wave, you went to -- how long was Third Wave in business before you arrived?
A. It started '94, and I believe it went public in 2000.
Q. Do you know what the business of Third Wave was when Third Wave started?
A. First was technology development in business, and in 2000 Third Wave started to sell reagents to research customers.
Q. And could you continue after 2000?
A. In 2002-2003 company started develop analyte

specific reagents for diagnostic customers.
Q. And what did it begin doing after 2002 and 2003?
A. What did --
Q. Third Wave, did Third Wave continue to develop products or continue to progress after 2002-2003?
MR. HANKINSON: Objection to form.
A. Yes. It continued to progress.
Q. And what did it move from in 2002 forward?
MR. HANKINSON: Objection to form.
A. Continues to develop products, and company was acquired in 2008.
Q. You said the company started with technology development. Did I understand that correctly?
A. Yes. It was a pure startup, a spinoff from University of Wisconsin, Madison and company spent first several years refining and developing technology.
Q. Do you know when Third Wave sold its first FDA cleared product?
A. That must be 2004 or 2005.

Q. After Third Wave, you went to EraGen. Is that correct?
A. EraGen, correct.
Q. Why did you leave Third Wave for EraGen?
A. I got better offer.
Q. That's a good reason. What was the business of EraGen?
A. Developing for analyte specific reagents diagnostic customers and drug discovery and developing products for FDA clearance.
Q. What type of analyte specific reagents did EraGen make for diagnostic customers?
MR. HANKINSON: Objection to form.
A. What type of products?
Q. Yes.
A. Bordetella pertusis.
Q. Say that again.
A. Bordetella pertusis, influenza, human herpes virus type 1, type 2.
Q. Anything else?
A. There might be more. I cannot remember all of them.

Q. Okay. Who were the customers for EraGen's analyte specific reagents?
A. CLIA certified laboratories for virology and microbiology.
Q. What would the CLIA certified lab -- how would they use EraGen's analyte specific reagents.
A. First of all, they have to bring those tests in-house and do extensive validation studies to make sure the reagents will fit their format. And then, under CLIA regulation, they can use them to report patient results.
Q. And the analyte specific reagents not FDA cleared, correct?
A. Correct.
Q. You also said that EraGen made products for FDA clearance?
A. The first product was approved for human virus 1 and human virus 2. So the whole development program was set up to make products that would eventually go through FDA clearance, meaning design control, design history file, all regulations, all certifications, quality control

analysis, acceptance, and so on and so forth.

Everything as a part of analyte specific reagents product was geared up to drive these products through FDA. Same regulations and same requirements were applicable to Third Wave Technology, product manufacturing, design and Visible Genetics so all for ASR remains the same.

Q. Say that again.

A. All for analyte specific reagents remains the same: Development, quality, manufacturing regulations.

Q. When did EraGen sell its first IVD FDA cleared product?

A. It was after my time with EraGen. I do believe the first clearance of product was in 2010.

Q. When did EraGen start as a company?

A. Cannot answer exactly this question. I can only guess it was before 2000.

Q. And why do you say before 2000?

A. Because I know a person who went to this company in 2000.

Q. Can you describe what the business was at EraGen from 2000 up to 2010 when it had its first FDA cleared product?

MR. HANKINSON: Objection to form. Vague.

A. First few years company spent on development and refining its proprietary technology. Later company build capabilities and all infrastructure to develop analyte specific reagents and go to FDA submission for approval so the whole infrastructure and everything was put in place.

Q. When did EraGen put in the infrastructure to go to the FDA?

A. I started with EraGen 2006. We had vice president of quality and regulatory, we had quality associates. In essence, in 2006 -- in 2006 when I started with EraGen infrastructure was in place.

Q. Do you know when EraGen sold its first products to customers?

A. I know we had sales to customers in 2006.

Q. Do you know how far before -- or do you know if EraGen was selling products from 2006?
A. Do not know. When I joined EraGen was very small.
Q. What types of products was EraGen selling in 2006?
A. Analyte specific reagent.
Q. During your time at EraGen, did you have any interactions with Illumina?
A. Yes.
Q. And in what capacity?
A. I was vice president of research and development.
Q. And how did your position as vice president of research and development at EraGen cause you to come into contact with Illumina?
A. I believe it was 2007 when we had discussions with Illumina on putting EraGen chemistry into Illumina BeadXpress machine.
Q. Other than those discussions during your time at EraGen, did you come across Illumina in any other ways?

A. We went and we saw your guys in San Diego, and I believe the entire team from Illumina, including your CEO, was at EraGen.
Q. Did you -- other than the discussions that you just mentioned, did you encounter Illumina in the marketplace in any other ways?
A. What time period are you talking about?
Q. During your time at EraGen.
A. No.
Q. And in 2009, you came to Meridian. Is that correct?
A. This is correct.
Q. Why did you leave EraGen to go to Meridian?
A. I got better offer.
Q. Your first position was VP of R & D at Meridian?
A. This is correct.
Q. From 2009 to 2007?
A. Yes.
Q. What were your responsibilities as VP of R & D?
A. Whole scope of research and development activities for Meridian, developing products and driving them through FDA.

Q. What about -- well, in 2007, you were promoted to senior VP. Is that correct?
A. Correct.
Q. Did your responsibilities change?
A. No.
Q. 2012 to present, you have been the executive vice president of R & D?
A. Correct.
Q. Did your responsibilities change when you became executive vice president of R & D?
A. No.
Q. Did you or have you had any responsibility for the ILLUMIGENE or ILLUMIPRO products while at --
A. Yes.
Q. What were your responsibilities with respect to those products?
A. Develop those products and have FDA clearances for them.
Q. Had work begun on the ILLUMIGENE and ILLUMIPRO products before you came to Meridian, sir?
A. This is correct.

Q. How far along was the development when you came to Meridian?
A. Work started in 2006.
Q. What was left to be done when you came to Meridian with respect to the ILLUMIGENE and ILLUMIPRO products?
MR. HANKINSON: Objection to form.
Q. Was anything left undone when you came to Meridian with respect to the ILLUMIGENE AND ILLUMIPRO products?
A. Develop product, conduct clinical trials, do FDA submission to receive clearance.
Q. Was there anything left to be done on the development side when you came to Meridian?
A. As I said, yes, develop product.
Q. What was left in the development side? It started in 2006, and you came in 2009.
A. Develop reagents.
MR. HANKINSON: Objection.
Q. Pardon? Develop reagents?
A. (Nodding affirmatively) Incorporate them in design control process, conduct clinical trials.

Q. During your time at Meridian, other than this proceeding, have you had any interaction with Illumina?
A. No.
Q. Have you come across Illumina at all in the marketplace other than -- putting this proceeding aside.
A. No.
Q. Are you familiar with a technology called LAMP technology?
A. Yes.
Q. That's the technology used in the Meridian ILLUMIGENE ILLUMIPRO products?
A. Yes, correct.
Q. Do you know when LAMP technology was developed?
A. In 2000.
Q. Do you know whether LAMP technology has been put to use besides in Illumina's -- sorry in Meridian's products?
A. Technology was developed by Eiken Chemical in Japan. Eiken came, gave licenses to several companies for this technology.

Q. Do you know whether LAMP technology was used for research purposes before it was commercialized?
A. There are many articles for LAMP technology for research use.
Q. Do you know what the research uses are for LAMP technology?
MR. HANKINSON: Objection to form.
Q. You can answer.
A. This is technology. This is on complication technology. People can use it for different application.
(Elagin Exhibit 2 marked for identification.)
BY MR. HORNE:
Q. I would like to talk about the recitation of goods for Meridian's trademark application. You have marked to your declaration -- do you want to look at Exhibit 2 in front of you?
A. Can I have break before we go over this?
Q. Sure. Let's take a break.
A. Great.

(Recess had.)

BY MR. HORNE:

Q. First of all, do you recognize Exhibit 2?

A. Yes, I do.

Q. It is a declaration you signed on February 5th, 2015 --

A. This is correct.

Q. -- in this matter?

A. Yes.

Q. Paragraph 11, you discuss Meridian's recitation of goods for its ILLUMIGENE and ILLUMIGENE molecular simplified and design registrations. Are you with me?

A. Yes.

Q. And then you make some statements about those or that recitation of goods.

I want to ask you questions about your statements. Okay?

A. Okay.

Q. The first statement is the second sentence of paragraph 11 where you say "one with applicable scientific education and/or experience would

understand this recitation to describe IVD products because the goods described are diagnostic kits that are to be used in testing and treatment."

Why would one understand that description to refer to IVD products?

A. Because it has diagnostic kits.

Q. So do IVD kits in diagnostic products mean the same thing?

MR. HANKINSON: Objection to form.

Q. What about the term "diagnostic kit" tells you that it would be an IVD product?

A. First of all, "diagnostic" meaning for testing and treatment, and "kit" means complete package, complete package of product that will be used for this diagnostic purpose.

Q. That tells you it means an IVD product?

A. It does mean that this is IVD product.

Q. Is it possible to have a diagnostic kit for testing and treatment that is not an IVD product?

A. You can have diagnostic reagent that could be

used. You can have diagnostic pieces that could be used, but in my mind, diagnostic kit means whole package of entire product. So you don't need to add anything else to it to conduct this diagnostic experiment or diagnostic test.

Q. Next sentence you say "moreover, the term 'molecular assays' in this context would be interpreted by one with skill in the field to mean amplification/detection test for microbial, viral, or other disease-causing agents."

My first question is: Where do you get the meaning to be amplification/detection test?

A. Molecular assays are assays that will work with DNA or RNA, and they will be for use to detect and the list is in my recitation, treatment of gastrointestinal, viral, urinary, so and so forth.

Q. But how do you get from molecular assay to amplification? I don't see "amplification" in the recitation of goods. So what does the term "molecular assay" mean you are amplifying?

A. Amplification or detection, but you are doing DNA or RNA amplification.
Q. Does it have to be amplification?
A. Not all the time. It is either amplification/detection or just detection.
Q. And then, the end of that sentence, you say it is an amplification/detection test for microbial, viral, or other disease-causing agents.
A. Yes.
Q. And why do you think the recitation of goods -- are you saying the recitation of goods is only for microbial, viral, or other disease-causing agents?
A. We have a list of agents in the recitation: gastrointestinal, viral, urinary, respiratory, and infectious diseases. That's what it is.
Q. And you are saying --
A. Microbial, viral, other disease-causing agents.
Q. So you are saying the recitation of goods can only mean microbial, viral, or other disease-causing agents?

A. Yes.
Q. Well, it says respiratory disease in the recitation of goods, right?
MR. HANKINSON: Objection to form.
A. Yes, yes.
Q. Okay. Is cystic fibrosis a respiratory disease?
A. No.
Q. It is not?
A. It is not.
Q. Why do you say "cystic fibrosis" is not a respiratory disease?
A. Because in terminology, respiratory disease is a disease that would be caused by viral, bacterial, or other disease-causing agent. Cystic fibrosis would be in category of inherited genetic disease.
Q. What about the terminology in the recitation of goods distinguishes a microbial, viral, or other disease-causing agent from an inherited disease?
MR. HANKINSON: Objection. Asked and answered.
A. Could you repeat it again.

Q. Sure. Could you repeat the question, please?

(Question read.)

A. Inherited disease is human DNA. Microbial, viral bacteria DNA is DNA from other than human.

Q. Where in the recitation of goods -- what causes you to interpret the recitation of goods to mean a disease other than human?

A. Treatment of gastrointestinal, viral, urinary, respiratory, and infectious disease.

Q. What about that terminology tells you it can't be a human disease?

MR. HANKINSON: Objection to form.

A. You said something I am not -- I don't agree. You just said what tells you it could not be human diseases. Could you explain what you just said? So those diseases caused by microbial, viral, agents they are human diseases.

Q. I guess my question is: What about the recitation of goods -- and I will ask a foundational question -- are you testifying in your declaration in here, in the deposition that

the recitation of goods for the ILLUMIGENE and ILLUMIGENE molecular simplified registrations is referring to only microbial, viral, or other disease-causing agents?

A. Yes.

Q. And what is your basis to make that statement?

A. Based on the disease testing for gastrointestinal, viral, urinary, respiratory, and infectious disease.

Q. So let's use "respiratory" for an example. Are you saying all respiratory diseases are microbial, viral, or come from another disease-causing agent?

A. In this context, yes.

Q. What do you mean by "this context"?

A. Because respiratory diseases causing by other agent.

Q. But what about the recitation of goods tells you it has to be caused by another agent?

A. Gastrointestinal, viral, urinary, respiratory, and infectious diseases.

Q. Why can't the respiratory disease in the

recitation of goods, why can't that be cystic fibrosis?

MR. HANKINSON: Objection. Asked and answered.

A. This is human inherited disease not caused by other agent.

Q. And I will ask one more time: What about the recitation of goods tells you that the diseases listed in that cannot be a human inherited disease?

MR. HANKINSON: Objection. Asked and answered.

A. Because it says testing and treatment of gastrointestinal, viral, urinary, respiratory, and infectious disease.

Q. Can't there be a human inherited respiratory disease?

MR. HANKINSON: Objection. Asked and answered.

A. Respiratory uses, when you are talking about respiratory uses in the clinical context means it was causing by other agent; bacteria viral

agent. If I am talking about cystic fibrosis, I will be more in the category of inherited human diseases.

Q. And in the category of inherited human diseases, can that be clinical?

MR. HANKINSON: Objection to form.

A. Category of --

Q. Can human inherited diseases be characterized in the clinical aspect?

MR. HANKINSON: Objection to form.

A. Yes.

Q. So then, why would somebody exclude human inherited disease from the possibility of the diseases listed in the recitation of goods for the ILLUMIGENE and ILLUMIGENE molecular simplified registrations?

A. Because those diseases are caused by other disease-causing agent, microbial, viral, and other disease-causing agents.

Q. Just because?

MR. HANKINSON: Objection to the form.

A. It says "other causing agents."
Q. Where does it say "other causing agents" in the recitation of goods?
A. Gastrointestinal, viral, urinary, respiratory, and infectious diseases.
Q. What in those words means other disease-causing agent?
A. Infectious diseases.
Q. Okay. Infectious disease means other disease-causing agent.
A. (Nodding affirmatively.)
Q. But there is the word "and." Are you saying infectious disease applies to gastrointestinal, viral, urinary, respiratory, and infectious diseases?
MR. HANKINSON: Objection to form.
A. Gastrointestinal, viral, urinary, respiratory, and infectious diseases.
Q. Okay. So are you saying that the respiratory disease listed in the recitation of goods has to be an infectious disease?
MR. HANKINSON: Objection. Asked

and answered.

Q. You said yes?

A. Based on the disease-causing agents, yes.

Q. Why does the respiratory disease have to be an infectious disease caused by a disease-causing agent?

A. By definition what this means, a disease caused by other agent.

Q. Okay. So are gastrointestinal diseases only caused by microbial, viral, or other disease-causing agents?

MR. HANKINSON: Objection to form.

A. Gastrointestinal diseases could be caused other than microbial, viral, or other agents.

Q. Could viral diseases be caused by something other than microbial, viral, or other disease-causing agents?

A. You repeated "viral" twice. Could viral usually be caused by viral?

Q. Fair enough. Could urinary diseases be caused by something other than a microbial, viral, or other disease-causing agent?

A. Definition of urinary disease is mostly, it is due to viral, microbial disease-causing agent.
Q. So the only type of urinary disease would be caused by a microbial, viral, or other disease-causing agent?
A. No. This is not correct.
Q. Why is it not correct?
A. Might be other form of diseases.
Q. Other than microbial, viral, or other disease-causing agent?
A. Yes, that is correct.
Q. And can a respiratory disease be caused by anything other than a microbial, viral, or other disease-causing agent?
A. Respiratory disease definition is diseases caused by other microorganism, viral, microbial, disease-causing agent.
Q. Would you go to Paragraph 12, please?
A. Same page?
Q. Yes. And here you discuss the ILLUMIPRO and ILLUMIPRO-10 applications there, and you might want to take a second to read those.

A. Yes.
Q. What does "closed tube" mean?
A. Means amplification will be conducted within closed tube.
Q. The last two sentences of Paragraph 12, you say "to one skilled in the field, these words mean that the tests being run are used for detection of disease in patients" paren "as opposed to analysis for research" end paren. The amplification and detection in such an assay keys one with the requisite knowledge to know this."

And why does or do the terms "amplification" and "detection" key one to know that the test is being run for the detection of disease in patients?
A. Because it says diagnostic machine in the beginning.
Q. Okay. So it is the term "diagnostic machine" that is keying you in, not the terms "amplification" and "detection"?

MR. HANKINSON: Objection to form.

A. Says amplification detection in such assays, continuation of second phrase if you read it.
Q. Could a machine that is used for amplification and detection be used in analysis for research?
MR. HANKINSON: Objection to form.
A. It depends.
Q. What would it depend on?
A. Depends on what type of machine, depends what type of technology, depends what form of quality and manufacturing control structure it is. It all depends on regulations. And it also depends on the company, whether they will or will not support those research machines.
Q. So it is possible then?
MR. HANKINSON: Objection.
A. Is it that diagnostic machine -- I cannot remember the second part of your question.
Q. I didn't say "diagnostic machine."
Is it possible that a machine used for amplification and detection can be used in analysis for research?
A. It is possible, yes.

Q. Thank you. Let's discuss the Illumina registrations, and could you turn to paragraph 14 of your declaration, please? The first registration is registration No. 2471539, and you quote the recitation of goods in your recitation. Would you take a moment to review that recitation of goods?

A. I'm sorry. We are --

Q. We are moving forward, paragraph 14?

A. I was looking on page 14. Okay.

Q. I may have said that by mistake. I apologize if I did.

Do you believe that the recitation in Illumina's registration No. 2471539 is vague?

A. Yes.

Q. Why do you believe it is vague?

A. It does not describe exactly what this is about. It says developing to the order and specification of others, chemical sensing systems, it is not quite clear what it is, random technology, and it has all broad

statement of organic and inorganic molecules or compounds or substance.

Q. Could you tell me what information could be put into that recitation to make it unvague for you?

MR. HANKINSON: Objection to form.

A. I will probably will need time to do so. It feels vague to me, and I am many not a lawyer.

Q. The top of page 5, we are still on paragraph 14, you say "one who of skill in the field would understand immediately that Illumina is describing the development of complex, custom made equipment."

A. Uh-huh.

Q. What about the recitation tells you the equipment is complex?

A. Sensing system, which use random array technology.

Q. Could you look at the recitation of goods for the ILLUMIPRO marks in paragraph 12. Are you there?

A. Yes.

Q. Does the recitation in Paragraph 12 for the ILLUMIPRO goods, does that describe complex equipment?
A. It described heater and turbidity meter, which is very simple detection system by itself, by default.
Q. The next sentence on paragraph 14, the second full sentence at the top of page 5, you say "he or she would recognize that nothing in Meridian's's trademark registrations and applications refers to any good or service that would use random array technology."
A. This was correct.
Q. Do you have any experience with random array technology?
A. Hands-on experience, no.
Q. Do you have anything else besides hands-on experience with random array technology?
A. General scientific knowledge.
Q. How did you gain your general scientific knowledge of random array technology?
A. Manuscript.

Q. Anything else?
A. That will cover it.
Q. When did you read the manuscripts regarding random array technology?
A. I cannot remember this.
Q. Was it for the purposes of this proceeding?
A. No, not at all.
Q. Can you give me an order of magnitude of how long ago it was, ten years, fifteen years, five years?
A. Illumina used random array technology for half my project that we discussed before.
Q. Could the goods described in Meridian's ILLUMIGENE registrations be used in connection with random array technology?
A. No.
Q. Why not.
A. Because it said it is -- because it is a turbidity meter and a heater.
Q. Okay. I am talking about the ILLUMIGENE registrations; not the ILLUMIPRO. Where does the ILLUMIGENE --

A. I'm sorry. One more time.
Q. Yeah. I will ask the question again.
Could the goods described in Meridian's ILLUMIGENE registrations be used in connection with random array technology?
A. It was described in ILLUMIGENE --
Q. Correct.
A. -- registration. That's what I am saying. That's what I was answering to you before.
Q. Okay. And your answer is no?
A. No.
Q. Why not?
A. Because ILLUMIGENE registration used closed turbidity in here.
Q. Where in the ILLUMIGENE recitation -- what in the ILLUMIGENE recitation tells you that it relates to turbidity?
A. Turbidity meter.
Q. That's in the ILLUMIPRO recitation; I am talking about the ILLUMIGENE recitation in paragraph 11.
A. I'm sorry. I'm sorry. My mistake.
Q. That's okay. Trust me, I will make many

mistakes throughout the day. So cut me some slack; I will cut you some.

A. So what was the question again?

Q. One more time: Could the goods described in the ILLUMIGENE recitation, which you have quoted in paragraph 11 of your declaration --

A. Okay.

Q. -- could those goods be used in connection with random array technology?

A. Could they be used for random array technology? Yes, they could.

Q. Next sentence you say "the definition of random array technology is vague and requires additional explanation."

What is vague about the term "random array technology"?

A. There is no description about technology by itself. Just saying "random" and "array" means microarray in that case.

Q. The next sentence says "my understanding is that the term 'random' implies that a system has random access for a sample input and 'array'

means microarray technology."

The first part of the sentence, when you say it is your understanding of "the term 'random' implies the system has random access for sample input," what do you base that understanding on?

A. My general description of what people saying random, random technologies, random sampling.

Q. When you say "your understanding," how confident are you in that understanding?

A. That's what I know.

Q. I appreciate that's what you know. How confident are you --

A. Confident.

Q. -- that your understanding of term "random" is correct as written on page 5 here?

A. It will be either random sample or random detection system. That's why it is very hard to judge from this statement. That's why I am saying it is vague.

So with this, random applicable to sample input, random access, random data

analysis? And it is not described in this recitation. That's why it is vague.

Q. A few sentences down you say "this technology is completely different the from the ILLUMIGENE technology, which utilizes a single analyte amplification detection by turbid --

A. Turbidemetry.

Q. Turbid --

A. Turbidemetry.

Q. Are you referring in that sentence to the actual technology as commercialized by Meridian, or are you referring to the recitation of goods in paragraphs 11 and 12?

MR. HANKINSON: Objection to form.

A. LAMP technology was developed in 2000 on turbidemetry. I am using broad terms. I am referring to broad technology statement.

Q. What do you mean by broad technology statement?

A. I am answering your question what I am referring to.

Q. Okay. So in the sentence where you say "this technology is completely different from the

ILLUMIGENE technology, which utilizes a single analyte amplification and detection by turbidemetry" --

A. Yes.

Q. -- you are referring to the concept of LAMP technology in general?

A. I am referring to ILLUMIGENE technology as a part and the concept in general, both.

Q. Not the recitation of goods in paragraph 11?

MR. HANKINSON: Objection to form.

A. The recitation of goods in paragraph 11 and technology in general.

Q. Okay.

A. So -- okay.

Q. Were you going to say something?

A. I was about to tell you that this technology is general, completely different from microarray technology in the big scheme.

Q. What about the recitation of goods in paragraph 11 tells you that it is a single analyte amplification?

A. It does not.

Q. And what about the recitation of goods in paragraph 11 tells you that it uses turbidemitry?
A. It does not.
Q. Further down, second to last sentence on page 14, still page 5, you say "moreover Illumina-branded products are in a different field of endeavor with different consumers - consumers were looking not for ready made IVD tests and locked IVD software on readers of those tests, but rather for open platform research equipment that customers can tweak, certainly RUO products, not IVD products."
My first question is: How do you know who Illumina's consumers are?
A. Because I had exposure with Illumina as a company; because I am working in the IVD field, and I know who our consumers are.
Q. Anything else?
A. That's good for now.
Q. What exposure with Illumina are you referring to?

A. My previous interactions as a company and knowing where Illumina business is in the field right now.
Q. So we have a clear record, can you explain what you mean when you say your previous interactions with Illumina as a company?
A. So I was working at Third Wave Technologies, and I know what Illumina sold as a research use only products before. I was working at EraGen Biosciences, and I know what state of business or what Illumina was selling at this point in time and just general knowledge where all companies are as of today.
Q. How do you gain your general knowledge as to where Illumina is today?
A. That is public information, websites and stuff like this.
Q. In the sentence I just read from your declaration, you refer to equipment that customers can tweak. What did you mean by that?
A. Change software, update software, change

reagents.

Q. Are you referring to customers using Illumina's products in LTDs in this sentence?

A. I am talking about mostly products that Illumina sells, most market what Illumina sells probably would be research use market.

Q. Okay. But when you say the customers can tweak, when you say customers can tweak, does that include using the Illumina product in an LDT?

MR. HURST: Objection to form.

A. Yes.

Q. Do consumers that create LTDs also buy ready-made IVD tests?

MR. HANKINSON: Objection to form.

A. They could.

Q. Next sentence you say "the random array technology described in this recitation implies such open-platform research equipment that is used by consumers separate and distinct from the ready-made kits identified in Meridian's ILLUMIGENE recitations."

A. Uh-huh.
Q. And what about the recitation in Illumina's registration No. 2471539 tells you that it is for open-platform equipment?
A. Developing to the order and specification of others. You have to look at the whole sentence --
Q. Okay.
A. -- as a whole.
Q. And why are you saying that it is for research equipment?
A. Developing to the order and specification of other. It is not ready-made up and down hardware and so forth.
Q. Okay. But could the equipment be used for an LDT?
A. This is a very broad question. It requires customer sophistication. It requires validations from the customer side. If you are asking this question with a specific qualification, if customer qualifies it, if customer is very specific, the answer is yes, it

could.

Q. And if the customers meet those qualifications, the products in this recitation 2471539, could they be used in a diagnostic LDT?

MR. HANKINSON: Objection to form.

A. I cannot answer this question because I am not quite sure what their technology doing in terms of analytes and in terms of detection. It says, DNA, RNA, and organic compounds, what kind of sophistication and what kind of work needs to be done. If you can give me what kind of analytes are you referring in that case, I might answer your question better.

MR. HANKINSON: Is this a good time for a break?

MR. HORNE: Sure.

(Recess had.)

MR. HORNE: Back on the record.

BY MR. HORNE:

Q. Can you turn to paragraph 15 of your declaration, please, and I can tell you I am going to ask some questions about -- some

statement you make in paragraph 16 referring to the recitation of goods for Illumina's registration No. 2756703. So you may want to read that recitation.

A. Okay. I have read both recitations right now. Should I read paragraph 16?

Q. You said you read both?

A. Yeah.

Q. Okay. We will go to paragraph 16.

A. All right.

Q. For simplicity, I might refer to the registration No. 2756703 as just the -703 registration. Do you understand what I am referring to if I say the -703 registration?

A. Yes.

Q. In the second sentence of paragraph 16, you say "the first recitation," and when you say "the first recitation," are you referring to the -703 registration?

A. Yes.

Q. Okay. You say "the first recitation describes types of equipment that are used in scientific

research and cassettes, specifically including molecular sensing optical fiber bundles."

And I want to focus on the first clause where you say "the first recitation describes types of equipment that are used in scientific research."

What causes you to conclude that the recitation in the -703 registration describes equipment used in scientific research?

A. Well, read the first sentence in this recitation. What does it say? "Scientific equipment and instruments and" dot dot dot dot dot dot.

Q. Uh-huh. Why would that be limited to scientific research?

MR. HANKINSON: Objection to form.

A. Okay. Let me read it for you and see what you would think.

Q. Okay.

A. "Scientific equipment and instruments, namely scanners, hybridization stations and fluidics delivery and computer systems," so you are

talking about five to six different pieces that could be combined together or be separate or anything, and it says point blank "scientific equipment and instruments," which will detect everything under the sun at the end of the sentence.

If you doing something for nucleic acids -- there is new defined product here. It is a combination of different pieces pooled together, so where else could it be used? Only in scientific research.

Q. Further down in paragraph 16, you say "Illumina's recited products are scientific equipment and specifically for analyzing the biological material at issue in a multiplex scale by employing optical fiber bundles, that is, specifically identifying and characterizing it, not amplification and detection of a single analyte with the heat and turbidity approach utilized by Meridian's goods."

A. Yes.

Q. My question is: Why does the term "analyzing"

in the -703 recitation of goods mean to identify and characterize material at issue?

MR. HANKINSON: Objection to form.

A. Could you please repeat it again?

Q. Sure. I am looking at the sentence where you are referring to -- correct me if I am wrong -- the -703 recitation of goods, right?

A. Yes.

Q. And it says "Illumina's recited products are scientific equipment and specifically for analyzing the biological material at issue in a multiplex scale by employing optical fiber bundles, that is, specifically identifying and characterizing it, not amplification and detection of a single analyte."

A. Yes.

Q. So what in the recitation of goods leads you to believe that the biological material at issue is being identified and characterized?

A. "Scientific equipment and instruments, namely scanners, hybridization stations and fluidics delivery and computer systems sold as a unit and

cassettes containing molecular sensing optical fiber bundles for analyzing?"

Q. Well, why does that mean characterizing instead of amplification and detection?

A. You could have analyzing sales products, could be million different ways of analyzing sales products and things like this. It does not specifically say amplification and detection.

Q. Okay. Could it be amplification and detection?

MR. HANKINSON: Objection to form.

A. If you will define for me better product that is here, I might offer an opinion. So far it is a combination of equipment and instruments, scanners, fluidics delivery, cassettes. So your question is extremely vague. That's what I am trying to say.

Q. Well, you are making a statement about the recitation of goods here, aren't you?

A. I do, yes.

Q. Okay. So what in the recitation of goods leads you to believe that they are describing, identifying, and characterizing biological

material --

A. It tells me what is described here is not amplification and detection of single analyte because you have such a complex description of different instruments and different platforms.

Q. Okay.

A. If you look what I said, amplification and detection of single analyte in the heat and turbidity approach. That's what the sentence is about.

Q. Okay. I am with you on the amplification and detection of a single analyte with the heat and turbidity approach.

A. Okay.

Q. Is it your testimony that the recitation of goods, if you put aside the heat and turbidity approach, is it your testimony that the recitation in the -703 could not be used for amplification and detection of a single analyte?

MR. HANKINSON: Objection to form

A. This equipment sounds to me it is very big and very expensive. Not a single person will buy quarter million-dollar equipment to do single analyte amplification and detection. It is practically a very, very strange approach.

Q. Not quite my question though:

Could the goods recited in the -703 registration be used for amplification and detection as a single analyte?

MR. HANKINSON: Asked and answered.

MR. HORNE: No, it wasn't.

MR. HANKINSON: It absolutely was. Do you want to argue with me, or do you want to move on with the deposition?

MR. HORNE: I want an answer to my question.

MR. HANKINSON: It has been asked and answered.

A. I don't know answer to this question because it says sensing and analyzing. I am not seeing any amplification in this sentence either, so it says equipment, hybridization stations, fluidics

delivery, computer system, so it could or could not. So I need to have more specific piece of information here.

Q. Go to paragraph 18. You say "considering Illumina's actual activity in the marketplace at the time of these applications and the first uses claimed in the registrations 2000-2003 and up through the 2008-2009 time frame, one with the applicable scientific background would understand that these recitations describe the detailed study and characterization of human genetic material in scientific research."

What activity in the marketplace are you referring to?

A. Illumina's actual activity, Illumina's products, services, what Illumina might in this particular time period.

Q. Do you know whether in this time period Illumina's products were ever used for something other than the detailed study and characterization of human genetic material in scientific research?

A. Define "other than," please. It is a very broad statement. It might be used as a paper weight. I do not know.
Q. Okay. Other than a paper weight, are you aware of any use?
A. I cannot answer this question "other than."
Q. So you are only aware up to 2008 and 2009 time frame, you are only aware of Illumina's products being used for the detailed study and characterization of human genetic material in scientific research?
A. Considering Illumina's actual activity -- let me put it different way: In 2008-2009, Illumina does not have IVD products in the market.
Q. Do you know whether by the 2008-2009 time frame Illumina's products were used in LDT?
A. I don't.
Q. If you go to paragraph 24, please, you say "all of the Illumina goods and services recitations, in light of Ms. Possemato's testimony and my scientific understanding, specify that the goods and services will be used in scientific

research, human genetic sequencing, or genotyping and specifically by using microarray assays."

Can you explain what you mean by that sentence?

A. Can I read couple sentences before?

Q. Absolutely. And for the whole deposition, if I point you to one sentence, if you need more context, feel free to do it. I just don't want to read the whole paragraph for everybody's sake.

(Pause.)

Q. (Continuing) And I should say, what do you mean by that sentence, I am focusing on when you say "specify that the goods and services will be used in scientific research, human genetic sequencing or genotyping, and specifically by using microarray assays." What do you mean by that clause?

A. In paragraph 21, Ms. Possemato's statement about scientific equipment, instrument, microarray technology is what she said in her recitation.

21.

Q. What line?

A. 21, second half of paragraph 21, please.

Q. What sentence?

A. She also testified that the "Illumina's recited scientific equipment and instruments are components and systems whose only use" -- and there is a reference to this testimony. If you want me to read it again, obviously, I am willing to do so.

Q. Okay. So your understanding of what is recited in the registrations is affected by Ms. Possemato's testimony?

MR. HANKINSON: Objection to form.

A. My understanding was recited to this testimony is what I testified in my testimony. In addition to her declaration, I think she has the same understanding as I do, what's in the recitation of these goods because, first, she was confused, and second, she said, hey, that's microarray research. So she come with my understanding on this case.

Q. Okay. So your understanding would be that the goods are all used in scientific research, and it is using human genetic sequencing or genotyping specifically by using microarray assays?

A. And bundle technology, hybridization, and computer systems and so on and so forth. And it was made to specification of others as it was in the good and services, very first phrase.

Q. So if you look at the recitation of goods in the -703 registration --

A. Yes.

Q. -- it doesn't refer to arrays at all, does it?

A. Microarrays and very first sentence "high throughput screening." You have optical bundles right here, and if you remember Ms. Possemato's testimony, once she started to talk about optical bundles, she immediately referred to my paragraph, and she was referring to product that Illumina was selling in 2000, 2004 that was discontinued that used microarray technology and

optical bundles in different platforms. I think it was Golden Gate technology that she was talking about.

Q. So does optical fiber bundles always mean microarray technology?

MR. HANKINSON: Objection to form.

A. It could or could not. It depends on the specifications in this case. But you have to take the whole sentence in context to understand what's it about.

Q. The whole -- what whole sentence?

A. The whole statement: "Scientific equipment and instruments, namely scanners, hybridization stations, fluidics delivery" and so on and so forth.

Q. So what about registration -703 tells you that it is using arrays?

A. Hybridization stations, fluidics delivery, and optical fiber bundles for analyzing.

Q. Why would that have to be array technology?

A. Array technology means you are doing multiple analyzing in the same test. Optical bundles,

hybridization stations and fluidics delivery tells you that you will do multiple analyzing in the same cassette or in the same piece of equipment if you wish.

Q. Could you accomplish this in a technology other than array technology?

MR. HANKINSON: Objection to form.

A. Scientific language, it will be called array technology. Even delivery or even instrument might be different, but it will be array.

Q. So putting aside Ms. Possemato's testimony, without that testimony, your reading of the -703 recitation of goods would require the use of array technology?

A. I don't understand the question. The technology, what it is here, it calls for array technology. It is probably a different, slightly different statement in your question.

Q. Okay. So the recitation of goods -- your testimony is the recitation of goods for the -703 registration necessarily means array technology?

MR. HANKINSON: Asked and answered twice. If you have a different answer to give, you can give it to me.

A. I don't have any other answer.

Q. That's yes?

MR. HANKINSON: Objection.

A. I said I don't have another answer other than I already answered twice.

Q. Okay. And are you saying in the first sentence of paragraph 24 that the recitation of goods for the -703 registration requires human genetic sequencing or genotyping?

MR. HANKINSON: Objection to form.

A. Can you read the sentence yourself? It says "in light of Ms. Possemato's testimony, my scientific understanding" -- so there is several logical steps here, right?

Q. In the -703 registration, what is your understanding of what it means when it says "analyzing cells, proteins, nucleic acids, and other molecules of 50 to 10,000 daltons"?

A. What is my understanding?

MR. HANKINSON: Objection to form.

Q. Yeah.

A. Of analyzing --

Q. Uh-huh.

A. My understanding of those complex instruments will use microfluidics, which will use optics, which will use computer station and hybridization and will analyze cells, proteins, nucleic acids, and other molecules.

Q. Does it have to include genetic sequencing or genotyping?

A. This is a very broad statement. It needs to be more specified. I cannot answer this question without difficulty, what it says in broad terms, analyzing.

Q. Is your understanding of the recitation of services for Illumina's -539 registration -- that was the first one we talked about in paragraph 14 -- is your understanding of that recitation affected by Ms. Possemato's testimony?

MR. HANKINSON: Objection to form.

Vague as to "affected by."

A. I do not know.

Q. Is it based upon Ms. Possemato's testimony?

A. Not based upon; it is my personal understanding of my testimony.

Q. What about your understanding of the goods in the -703 registration, is that based, at least in part, upon Ms. Possemato's testimony?

A. You are asking this question third time if you remember. I answered you this question already. I put my own testimony and Ms. Possemato's testimony just to confirm my additional understanding.

Q. Okay. In paragraph 25, the second sentence you say "the consumers of diagnostic kits and diagnostic machines are treating/clinical physicians looking for an inexpensive and quick way to confirm or deny the presence of a particular bacteria, fungus, or virus." What's a clinical physician?

A. You are asking me what clinical physician means.

Q. Yeah.

A. Physician that have a clinical practice.
Q. What do you mean by clinical practice?
A. So if you are going to hospital, you can see a pediatrician. A pediatrician does not have a clinical practice; is just a pediatrician. Or you can see the doctor that could have a clinical practice.
Q. Would you say that the consumers of Meridian's ILLUMIGENE and ILLUMIPRO products are physicians?
MR. HANKINSON: Objection to form.
A. Clinical physicians or treating physicians.
Q. Okay. What about clinical diagnostic labs would they be consumers of diagnostic kits and diagnostic machines?
A. It all depends what you mean by "consumer." In my sentence here, the consumer is a person who needs this result; not who did exact test. So what I am saying, that IVD products are diagnostic products.
Q. So when you say "the consumers of diagnostic kits and diagnostic machines are

treating/physicians," you are not necessarily saying those are the purchasers of the diagnostic kits and diagnostic machines?

A. Or run those tests.

Q. Yeah. That was going to be my next question.

A. They are not actually users.

Q. Who are the actual users of diagnostic kits and diagnostic machines?

A. This is broad question as you understand, right? So different kits, different diagnostic machines could be used by various departments within hospitals like virology, microbiology, human genetics, genomics. They might have different people with different degrees and different education, but the majority of them, the people who will supervise the laboratories will be highly educated people.

Q. So the same sentence you say "the consumers are the treating/clinical physicians looking for an inexpensive and quick way to confirm or deny a particular bacteria, fungus, or virus."

Are you testifying here that all

diagnostic kits and diagnostic machines are inexpensive?

A. Cost efficient probably would be better way to put it.

Q. Okay. Which could mean a variety of actual prices, correct, depending on the situation in which they are used?

A. If I want to detect or diagnose only single disease X, I will use a cost efficient instrument.

Q. And you refer to "quick way to confirm or deny the presence of a particular bacteria, fungus, or virus"?

A. Yes.

Q. Are you saying that there are no diagnostic kits sold to detect genetic issues?

A. This is example. The consumer of diagnostic machines, the people who will look for us.

Q. Are those people only looking to confirm or deny the presence of a particular bacteria, fungus, or virus, or could they also be looking at genetic issues?

A. A different physician might look for genetic issues, yes. But it will not be a virologist for that particular patient. So this is a sentence as an example what it is all about.

Q. Third paragraph, 27, please. The first sentence you say "in 2008, Illumina's products had zero presence inside a clinical diagnostic or microbiology laboratory."

What are you referring to when you say "clinical diagnostic laboratory"?

A. There is a definition in the second sentence.

Q. Okay. How could you know for certain that Illumina's products had zero presence inside a clinical diagnostic lab?

A. This is my knowledge.

Q. How is that your knowledge?

A. Based on my experience, on my work with different laboratories, and based on what I know about state of Illumina technology and the state of the art, so keep in mind, in 2008 Illumina does not have any IVD products.

Q. When you say "clinical diagnostic lab," are you

referring to all types of clinical diagnostic labs?

A. Clinical diagnostic labs, human body, very broad terms that will be submitted to physician for the testing.

Q. Is it possible that an LDT could be performed at a clinical diagnostic laboratory?

MR. HANKINSON: Objection to form.

A. If LDT tests undergo certifications and all regulatory assumptions for that particular case, they might.

Q. So then, if an Illumina product was used and as part of an LDT in that situation, an Illumina product could be used inside a clinical diagnostic lab, correct?

MR. HANKINSON: Objection.

A. This is wrong. You are saying Illumina product. It could be RUO product. It could be LTD product. There is something about diagnostic kits, the whole complete product, portfolio, meaning instrument is locked down, software is locked down, all reagents locked down, all goes

under IVD regulation, all FDA cleared, all goes to different regulatory requirements. We are talking about diagnostic kits meaning who packaged it.

Q. So when you say Illumina's products had zero presence inside a clinical diagnostic laboratory in 2008, you mean that Illumina sold no diagnostic kits that were FDA cleared to a clinical diagnostic laboratory?

A. Let me give you another example. So you have a company called Qiagen.

Q. Could you just answer that question before you give an example?

MR. HANKINSON: Objection. Please finish your answer.

BY MR. HORNE:

Q. Answer the question. Then you can please give me an example.

MR. HANKINSON: Objection. You need to let him finish, and then you can ask your question.

A. I am giving you another example of what it could

be.

Q. Okay.

A. So the Qiagen selling research reagents, and they were selling product for sample purification, it is not complete product or complete kit, which will do testing results or do any particular results. It could be part of 1, 2, 5, 15, 25 different procedures that laboratory could play around. But it is not a full product, which can go from a sample to test result. So "presence" is very broad term, you know.

Q. It is your term so --

A. Yes.

MR. HANKINSON: Is there a question pending?

Q. Is your answer complete?

A. I gave my answer.

Q. I don't think I got an answer to my question. I am talking about Illumina, your statement that Illumina's products had zero presence inside a clinical diagnostic laboratory. When you make

that statement, are you referring to the fact that Illumina did not sell an FDA cleared kit to a clinical diagnostic laboratory in 2008?

A. Performance diagnostic test, also referred as in vitro diagnostic or IVD test. It is right verification right here in parens. I didn't understand your question. I am sorry.

Q. So is it correct, then, that the first sentence in paragraph 27 of your declaration does not address whether an Illumina product was used as part of an LDT inside of a clinical diagnostic laboratory?

A. Correct. And I have no knowledge of that.

Q. Thank you. In kind of the middle of the paragraph 27, you say "in 2008 to 2009, Illumina's products and services were focused on research applications as research use only products and were not cleared by the FDA for in vitro diagnostic use."

And you say "these RUO products are used by academic laboratories" and then so on and so forth. The "are," are you still

referring to the 2008 to 2009 or what time frame are you referring to --

A. Yes.

Q. -- when you say "are"?

A. Yes.

Q. So to be more accurate, do you use the word "were" instead of "are" in that sentence?

MR. HANKINSON: Objection to the form.

A. If you ask me question where majority of products are used by Illumina right now, I will testify that those products, majority used in academic level -- so they were, and they are.

Q. When you say "majority," do you know any other places where Illumina's produces are sold or used?

MR. HANKINSON: Objection. Vague as to time period.

A. Time period is what?

Q. How about now?

A. Majority means majority.

Q. Okay.

A. I cannot put any more clarification.
Q. Do you know what other places? I am not asking you to put a percentage. I am asking what else -- majority doesn't mean all.
A. Let me -- I'll say it other way: During my career at Meridian, I never met any ILLUMIGENE product in our customer.
Q. When you say "ILLUMIGENE," you meant to say "Illumina," right?
A. Any Illumina product in our customer. Isn't that what I said?
Q. How do you define "our customers"? You mean Meridian's when you say our customers?
A. Meridian customers, customers who is using our product.
Q. Okay. What customers are using Meridian products?
A. Companies in the infectious disease area and then working with these customers in the virology, microbiology, biology, yes, majority of our customers.
Q. Paragraph 28 you say "in a small number of

medical institutions or much larger and well-funded institutions researchers in the research laboratory side do work that could be considered in one sense of the word diagnostic, but it is not through the use of IVD clinical diagnostic products such as Meridian's ILLUMIGENE products. Rather, in this small subset of laboratories, researchers create their own diagnostic assays from RUO parts and components or use RUO products to conduct medical research studies such as biomarker discoveries for different human diseases," paren "cancers, and inherited diseases, et cetera."

Are you referring to lab developed tests, LTDs in these two sentences?

A. No. That's two sentences talk specifically about research only products.

Q. And you say they could be considered in one sense of the word diagnostic. What do you mean by that?

A. Diagnostic means detection. It is a difference from a --

Q. Do you know in this sense, in these what you are referring to in the first sentence at paragraph 28, what these users are trying to detect?

A. I gave couple examples if you read the whole paragraph down. So cancer biomarkers would probably be the big deal for Illumina right now and high throughput, single nucleotide polymorphism sequencing, and so on and so forth.

Q. Are you testifying that the type of use that you refer to in the first two sentences at paragraph 28 are limited to researchers on the research laboratory side?

A. So I was talking about the sentence, which in conjunction is clinical diagnostic problems, and clinical laboratory could have a research side or research arm and could have an arm with different technicians who are using IVD FDA approved products.

Not every single clinical laboratory in the United States could afford

research arm. That's why I am saying small number of institutions or well-funded organizations who can conduct clinical trials. But majority of clinical laboratories in small hospitals, for example, will strictly use IVD products only.

Q. And in the situations in which a clinical lab does use RUO products to create their own diagnostic assays, are you saying that those are only used for research purposes?

A. I gave you example of Qiagen product. If it is CLIA certified laboratory and they have sufficient amount of sophistication and education, they might use some research only components to create their own product. Their own product, they have to control. They have to make sure that the expiration of materials is not expired, and they have to do majority of organization pieces. So these are your components, could be part of laboratory developed test.

Q. And this laboratory developed test that you just

explained, what would that be used for?

A. This developed test would be used for detection of human diseases in the clinical diagnostic lab, but keep in mind the laboratory has to have whole control entirely, from start to finish, or they can change one area of component to second area of component, and they can change different vendors for this case as well.

Q. If you can go to paragraph 29, please, first sentence you said "I have reviewed the deposition testimony of Illumina's employee Naomi O'Grady, who makes some relevant comments that I agree with on this particular topic."

Then two sentences down you say "at her deposition, she acknowledged that when laboratories use Illumina's components or equipment to make LDTs for a diagnostic purpose, the output of the laboratory is a test report sent by the laboratory to the ordering physician with no involvement from Illumina."

Can you explain what such an LDT for a diagnostic purpose would be used for?

MR. HANKINSON: Objection to form.

A. I'm sorry. You need to specify what you are referring to, this particular testimony. To her deposition? To my understanding of what she was referring to? Are you referring to her deposition, or are you talking about LTDs in general? Or are you talking about diagnostics in general?

Q. Okay. Well, when a laboratory would use an Illumina component to make an LDT for a diagnostic purpose and there is a test report that is sent to the ordering physician.

A. Okay. Laboratory will use a Illumina component, a reagent. Okay? So what's the question?

Q. For an LDT for a diagnostic purpose --

A. For an LDT for a diagnostic purpose. Okay.

Q. -- the output would be sent by the lab to the ordering physician.

A. Output will be sent to the lab by ordering physician.

Q. What type of diagnostic purpose would such an LDT be used for?

MR. HANKINSON: Objection to form.

A. I can't answer this question, but in order -- again, in order for laboratory to use Illumina component for LTD test, the laboratory has to create a whole full package of the product from start to finish. They have to create quality controls. They have to do extensive validations and verifications of those components, and they have to do all other regulatory activities to satisfy CLIA certification. And if they decided to switch from one component to another, they can do it as well.

Q. And if the lab met those qualifications that you just explained, it could use an RUO product as part of an LDT to diagnose a patient?

A. It cannot. RUO product communicates -- means the whole package. It can use an RUO component as a part of entire diagnostic kit, as a finished kit, meaning full proof. Component means part of it, which could be replaced as well.

Q. So if a CLIA certified lab using RUO component

as part of an LDT and that lab met the quality controls that you explained in your deposition, that LDT could be used by that lab to diagnose a patient, correct?

A. Yes. I will say if and with the proper qualifications as well, yes.

Q. At the end of paragraph 30, you say "that is why Illumina can have nothing to do with the test report. Its components are not FDA cleared as IVD products."

Are you aware of any regulation, or are you referring to any regulation here?

A. I am saying that based on Naomi O'Grady's testimony, referring to LTD test CLIA laboratories, laboratory has the whole control of the product. They took one component from one company, second component from second company, third component from third company. They created the whole package by themselves.

They did the all quality control systems, all validations, and there is a whole package. They are saying "that's my LDT test."

That's what I am saying.

Q. Okay.

A. And I might change one of the controls of the components later because I have whole control of this product and whole control of what I am doing to report patient result.

MR. HANKINSON: Are you going to do more on this topic, or are you going to try to finish --

MR. HORNE: Why don't we go off the record.

(Discussion held off the record.)

(Recess had.)

BY MR. HORNE:

Q. Would you turn to page 15, paragraph 39 of your declaration, paragraph 39, you say "because of the function and focus of the veracode genotyping test, users of that test would work in hematology or human genetics departments. This is in contrast to users of Meridian's ILLUMIGENE clinical diagnostics products who would be in infectious disease, virology, or

microbiology departments."

When you use the word "departments," what do you mean? Departments of what?

A. Hospital could have a different diagnostic department. Laboratory could have different departments. So departments, basically we are talking about virology department, microbiology department, hematology department and so on and so on. So that's a specialty of the laboratory to focus on this particular department.

Q. Do you have any understanding of how the different departments in a lab are or are not separated for lack of a better word?

A. Usually, there is a head of the department who is a specialty, like I am virologist. I am microbiology, or I am human genetics.

Q. How about physically structured, are they in the same room or different buildings?

A. They -- they obviously will be different locations; could be different buildings; could be different floors; could be the same floor but

separate room, all in a row.
Q. Could it be in the same room but different areas of the same room?
A. If it is a small hospital, very small hospital, which has restriction on number of tests ordered and restriction of personnel and space.
Q. How about with a reference lab, could a reference lab have the different departments located in the same room?
MR. HANKINSON: Objection. Calls for speculation.
A. Reference lab, same departments in the same room?
Q. Uh-huh.
A. My description was in general. I cannot answer your question.
Q. Okay. Next sentence in paragraph 39 you say "analyzing human genetics is a totally separate scientific field from detecting infectious diseases."
A. Sorry. Where are you?
Q. I'm sorry, paragraph 39 still. Last sentence:

"Analyzing human genetics is a totally separate scientific field from detecting infectious diseases"?

A. Uh-huh. Yes.

Q. Is there a separate human genetics department?

MR. HANKINSON: Objection to form.

A. This is broad question. Different organization could have a different structure.

Q. Okay.

A. But it is a totally different specialty, totally different person with a different experience and expertise.

Q. Okay. And there may or may not be, depending on the situation, there may or may not be a separate department for human genetics aside from infectious disease department?

MR. HANKINSON: Objection to form.

A. That's -- so you said maybe, maybe not, so -- you are not asking the question. You are saying maybe, maybe not, it might be.

Q. Okay. You can't speak definitively one way or the other. That's my question.

MR. HANKINSON: Objection to form.

A. Exactly.

Q. Paragraph 44.

MR. HANKINSON: Did you say 44?

MR. HORNE: Yes.

BY MR. HORNE:

Q. Last numbered paragraph of the declaration, "even after those Illumina products were cleared by the FDA, the clinical diagnostic community did not consider Illumina or its products to be competitive with Meridian and its products."

My question is: What's the basis for your statement?

A. So how you can be -- how can you have like a half million-dollar instrument be competitive with instrument that Illumina provide free. The cost is tremendous difference. The product menu, Illumina is focusing on infectious disease. Illumina is focusing on high throughput, expensive tests for massive parallel detection for human genetic or cancer diagnosis. So field is different; price is different.

Q. And you make some statements in paragraph 44, you refer to your Exhibit B of this slide presentation, and I understand the point you are making, but other than Exhibit B in your explanation and the remainder of paragraph 44, what's your basis to say what others in the clinical diagnostic community considered?

MR. HANKINSON: Objection to form.

A. Others -- where you pointing to?

Q. You say "the clinical diagnostic community." I asked what was your basis for you, Dr. Elagin, saying what other people thought.

A. Because --

MR. HANKINSON: Objection. Asked and answered. And as to form.

Q. Okay. You can answer.

A. I discussed and I know our customers, number one. I know what clinical community is doing because I was visiting conferences, trade shows, I was talking to our customers. I was physically working on what they were working, what they are doing.

That's why I think the clinical community doesn't have any confusion considering Illumina products. I am saying, this statement is saying even after those Illumina products were cleared, referring to 2010, I can tell you talking to customers today there is no confusion between Illumina products and Meridian products.

Q. Okay.

A. Not only in 2008, 2010 but 2015 as well.

Q. Okay.

MR. HORNE: Why don't we go off the record.

(Luncheon recess.)

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AFTERNOON SESSION

BY MR. HORNE:

Q. Welcome back.

A. Okay.

Q. Could you name the competitors for ILLUMIGENE -- I'm sorry for Meridian's ILLUMIGENE, ILLUMIPRO products?

A. Our biggest competitor would be Cepheid.

Q. Can you name any others?

A. Becton Dickinson. They are two major ones. There is probably a couple more as well.

Q. Could you identify a few more, or do you know?

A. Great Basin Technologies.

Q. B-a-s-i-n?

A. B-a-s-i-n. That's third biggest.

Q. What type of product does Cepheid sell?

A. They are selling product with a sample in-result out test.

Q. Let me ask the question differently:

Does Cepheid sell a separate kit and instrument similar to ILLUMIGENE AND

ILLUMIPRO?

A. Cepheid is selling FDA approved instrument and FDA approved kits similar to ILLUMIGENE.

Q. Do you know the name of the instrument?

A. SmartCycler.

Q. How about the name of the kit?

A. Cepheid diagnostic kit; cannot positively identify it.

Q. Do you know how much money Cepheid charges for its instrument?

A. They have several different models. Depends on high throughput, which would be like four samples at the time up to 48 and process charge will be from $20,000 all the way to quarter million dollars.

Q. That's for the high throughput?

A. Yes.

Q. Are there any cheaper machines or $20,000 is at the low end?

A. Becton Dickinson machine --

Q. I'm sorry. I am talking just Cepheid for now.

A. You said "Are there any?"

Q. I apologize. I meant did Cepheid have any smaller, any cheaper?
A. I saw in latest trade show recently they introduced model for one test and two tests. I don't know if they are sending them yet or not.
Q. Do you know what those cost?
A. No.
Q. Becton Dickinson, do they sell a separate kit and instrument?
A. They sell separate kit and sell separate instrument.
Q. And the name of the instrument?
A. BD Max.
Q. Do you know how much Becton Dickinson charges for the BD Max?
A. I believe it is in the $50,000 ballpark.
Q. How about the kit, do you know how much Becton Dickinson charges for its competitive kit?
A. Different customers, different pricing points, it is roughly about $20.

Q. How many tests come in a $20 kit?
A. One.
Q. Cepheid, do you know how much Cepheid charges for its competitive kit?
A. For one test $25 to $40.
Q. Great Basin, does Great Basin sell a separate instrument and kit?
A. Yes. Both kit and instrument FDA approved.
Q. Do you know the name of the instrument that Great Basin sells?
A. Don't remember.
Q. Do you know how much Great Basin charges for their competitive instrument?
A. In the ballpark of $20,000.
Q. How about Great Basin's kit, do you know how much they charge?
A. Same as others, $20, $30.
Q. For one test?
A. One test.
Q. The BD instrument, do you know how many samples it can test at a time?
A. Sixteen or twenty.

Q. How about the Great Basin instrument, do you know how many?
A. One.
Q. Earlier today I asked you some questions about whether a CLIA certified lab can use RUO components for a lab developed test to diagnose a patient.

Do you know whether such a CLIA certified lab, separate from an LDT, might also purchase and use FDA cleared IVD products?
A. CLIA certified lab?
Q. Uh-huh.
A. I don't know.

MR. HORNE: I have no further questions.

MR. HANKINSON: Just hold on. Won't be a minute but maybe a five-minute break. Sorry I didn't know you were going so short.

(Recess had.)

MR. HANKINSON: Shall we go on?

MR. HORNE: Yes.

MR. HANKINSON: I have some questions.

EXAMINATION BY COUNSEL ON BEHALF OF THE APPLICANT/REGISTRANT

BY MR. HANKINSON:

Q. Dr. Elagin, in a situation where a customer might be buying both IVD products and research use only components for use in a laboratory developed test, would you please describe the people who would be making those purchasing decisions?

A. It will be very sophisticated and educated people with typical degree, Ph.D. and M.D., who will know this field very well and have an extensive educational background.

Q. Does Meridian's competitors, Cepheid, Becton Dickinson, and Great Basin, sometimes provide the readers of their competitive kits to the customers at no initial cost?

MR. HORNE: Lacks foundation. Vague. Leading. You can answer.

A. In current situation in the marketplace as of

today and as of past five years, our competitors, Cepheid, Becton Dickinson, and Great Basin, do provide their instrument for free of charge, and it is called reagent rental program, providing the instruments for free and then by charging for kits and for products to collect back.

Q. This morning, do you recall Mr. Horne's questioning of you about the product and services recitations in Meridian's and Illumina's trademark applications?

A. Yes, I do.

Q. Do you recall some of the questions asking about specific words or phrases of a few words at a time?

A. Yes, I do.

Q. If those questions had asked you about the entire product or services recitation at issue, would your answers have been the same or different?

MR. HORNE: Vague.

A. My answers will be the same as in my

declaration, and they will be different from the questions that I was asked to answer.

Q. Did any of Mr. Horne's questions today cause you to change your mind, or would they cause you to change your testimony from the statements and opinions that you gave in your declaration?

MR. HORNE: Vague.

A. No. It is my declaration, and I not changing it from our discussions today.

MR. HANKINSON: That's all I have.

FURTHER EXAMINATION BY COUNSEL ON BEHALF OF OPPOSER/PETITIONER

BY MR. HORNE:

Q. I want to talk about the competitors that don't have an initial charge for the readers. Do you have an idea -- or do you know how often that happens?

A. The initial charge versus what?

Q. Well, I understood from your testimony just now that sometimes the competitors, Cepheid, Becton Dickinson, and Great Basin, do not --

A. Charge for instrument, correct.

Q. How often does that happen?
Let me ask you another question.
How do you know is the first question.
A. From discussion with our sales and marketing people from understanding what's going on in the field.
Q. How do your sales and marketing people know what other competitors are charging customers?
A. So there is a competitive sale, and we have this information. It is market intelligence.
Q. How do you get the information?
A. Interviewing customers.
Q. So a customer tells you what Cepheid charged for the instrument or didn't charge for the instrument?
A. There is information, it is called list price, and then customer is telling us how much they were paying for it.
Q. Do you have an understanding of how often Cepheid, Becton Dickinson, and Great Basin place the instrument at a customer without an upfront charge?

A. I cannot give you exact percentage.
Q. Uh-huh.
A. I can tell you this happens more often now than before.

MR. HORNE: I have no more questions.

MR. HANKINSON: I have one more.

FURTHER EXAMINATION BY COUNSEL ON BEHALF OF APPLICANT/REGISTRANT

BY MR. HANKINSON:
Q. Are the ways in which you know about the prices of competitors' readers the same ways in which you know that sometimes the competitors provide those readers to the customers at no initial cost?

MR. HORNE: Vague.

A. Yes, from discussions with customers. So we know some of them receiving those readers for free. Some of them are receiving those readers to pay some money upfront.

MR. HANKINSON: That's all.

MR. HORNE: Nothing further.

MR. HANKINSON: Well designate this -- we are still on, right?

THE REPORTER: Yes.

MR. HANKINSON: We will designate transcript of this deposition confidential provisionally under the protective order. We will review it and possibly dedesignate all or a portion of it.

(Signature not waived.)

(Deposition concluded at 2:04 p.m.)

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State of Ohio,)
) SS: CERTIFICATE
County of Cuyahoga.)

I, George J. Staiduhar, a Court Reporter in and for the State of Ohio, duly commissioned and qualified, do hereby certify that the within named witness, Vecheslav A. Elagin, was by me first duly sworn to testify to the truth, the whole truth, and nothing but the truth in the cause aforesaid; that the testimony then given by him was by me reduced to stenotypy/computer in the presence of said witness, afterward transcribed by me, and that the foregoing is a true and correct transcript of the testimony so given by him as aforesaid.

I do further certify that this deposition was taken at the time and place in the foregoing caption specified.

I do further certify that I am not a relative, counsel, or attorney of either party, or otherwise interested in the event of this action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Cleveland, Ohio, on this 11th day of March, 2015.

George J. Staiduhar, Notary Public in and for the State of Ohio. My commission expires August 1st, 2017.

Vecheslav A. Elagin c/o
KEATING MUETHING & KLEKAMP, PLL
One East 4th Street, Suite 1400
Cincinnati, OH 45202

Case: Illumina Inc. v. Meridian Bioscience, Inc.
Date of deposition: March 10, 2015
Deponent: Vecheslav A. Elagin

Please be advised that the transcript in the above referenced matter is now complete and ready for signature. The deponent may come to this office to sign the transcript, a copy may be purchased for the witness to review and sign, or the deponent and/or counsel may waive the option of signing. Please advise us of the option selected. Please forward the errata sheet and the original signed signature page to counsel noticing the deposition, noting the applicable time period allowed for such by the governing Rules of Procedure. If you have any questions, please do not hesitate to call our office at (202)-232-0646.

Sincerely,
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SIGNATURE PAGE

Case: Illumina Inc. v. Meridian Bioscience, Inc.
Witness Name: Vecheslav A. Elagin
Deposition Date: March 10, 2015

I do hereby acknowledge that I have read and examined the foregoing pages of the transcript of my deposition and that:

(Check appropriate box):
( ) The same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.
(X) Except for the changes noted in the attached Errata Sheet, the same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.

March 23, 2015
DATE

WITNESS SIGNATURE

March 23, 2015
DATE

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ERRATA SHEET

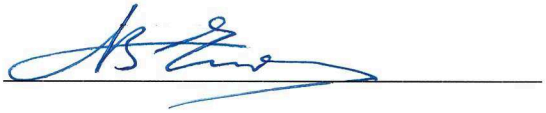
Case: Illumina Inc. v. Meridian Bioscience, Inc.

Witness Name: Vecheslav A. Elagin

Deposition Date: March 10, 2015

Page No. Line No. Change

Please see Errata listed on the attached APPENDIX A



Signature

March 23, 2015

Date

APPENDIX A to Errata for Vecheslav A. Elagin, Ph.D.

Page(s)	Line(s)	Correction
5	5	Change "Third Wave Technologies and EraGen" to "Third Wave Technologies and Stratagene"
5	12	Change "I was vice president of research" to "I was vice president of research and development"
5	16	Change "that EraGen infringed our patent" to "that Stratagene infringed our patent"
12	5	Change "companies like Rausch" to "companies like Roche"
12	6	Change "like Galaxy to "like Glaxo"
15	6	Change "We had a different problem" to "We had a different product"
16	1	Change "were competing with us" to "were customers with us"
20	9	Change "hepatitis C, genotyping" to "hepatitis C genotyping"
24	18	Change "human genome project" to "human genome HapMap project"
27	8-9	Change "Developing for analyte specific reagents diagnostic customers and drug discovery" to "Developing of analyte specific reagents for diagnostic customers and drug discovery"
27	16	Change "Bordetella pertusis" to "Bordetella pertussis"
27	18	Change "Bordetella pertusis" to "Bordetella pertussis"
28	17	Change "The first product was approved for human virus 1" to "The first product was approved for human herpes virus 1"
32	3	Change "your CEO, was at EraGen" to "your CEO Jay Flatley, was at EraGen"
36	10-12	Change "This is on complication technology. People can use it for different application." To "I said "This is an application technology. People can use it for different applications."
52	8	Change "feels vague to me, and I am many not a lawyer" to "feels vague to me, and I am not a lawyer"
53	22	Change "Manuscript" to "Manuscripts"
54	11	Change "Illumina used random array technology for half my project that we discussed before" to "Illumina used random array technology that was competitor for half of my projects that we discussed before"
61	1	Change "My previous interactions as a company" to "My previous interactions with a company"
62	11	Change "HURST" to "HANKINSON"
67	8	Change "there is new defined product here" to "—there is no defined product here."
69	5-7	Change "You could have analyzing sales products, could be million different ways of analyzing sales products" to "You could have analyzing these products, could be million different ways of analyzing these products"
72	16	Change "services, what Illumina might in this particular" to "services, what Illumina might sell in this particular"
75	17	Change "In addition to her declaration" to "In addition, in her declaration"
81	12	Change "testimony just to confirm my additional understanding" to "testimony just to confirm my initial understanding"
87	3-4	Change "talking about diagnostic kits meaning who packaged it" to "talking about diagnostic kits, meaning the packaged kit"
89	6	Change "right here in parents" to "right her in parenthesis"
91	6	Change "ILLUMIGENE" to "Illumina"

100	16	Change "is a specialty" to "has a specialty"
103	18	Change "Illumina is focusing on infectious disease" to "Illumina is not focusing on infectious diseases"
108	5	Change "sending" to "selling"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL APPEAL BOARD

ILLUMINA, INC.,	)	Opposition No. 91194218 (parent)
	)	Ser. No. 77/768176
Opposer/Petitioner,	)	
	)	Opposition No. 91194219
-v-	)	Ser. No. 77/775316
	)	
MERIDIAN BIOSCIENCE, INC.,	)	Cancellation No. 92053479
	)	Reg. No. 3887164
Applicant/Registrant.	)	
	)	Cancellation No. 92053482
	)	Reg. No. 3868081
	)	

DECLARATION OF VECHESLAV A. ELAGIN, PH.D., MBA

I, Vecheslav (Slava) A. Elagin, hereby state and declare as follows:

1. My name is Vecheslav A. Elagin, I am over eighteen (18) years of age, and I have personal knowledge of the facts stated in this Declaration.

My Background, Education and Experience

2. In 1988, I earned a Bachelors of Science degree in Applied Physics and Mathematics from the Moscow Institute of Physics and Technology in Moscow, Russia. In 1990, I earned a Masters degree in Genetics from the Vavilov Institute of General Genetics in Moscow, Russia. In 1992, I earned my doctorate in Molecular Genetics from the Engelhard Institute of Molecular Biology in Moscow, Russia. And in 2009, I earned an executive MBA from the University of Wisconsin in Madison, Wisconsin. I have worked as an academic in the field of molecular genetics, including as a Staff Scientist and Principal Investigator at the Institute of Gene Biology in Moscow, Russia from 1992 to 1996, and as a Research Assistant Professor at the University of Notre Dame in Indiana from 1996 to 2000.

3. I am currently employed by Meridian Bioscience, Inc. ("Meridian") as Executive Vice President, Research and Development. I have worked for Meridian since 2009, when I started as Vice President, Research and Development. In 2011, I was promoted to Senior Vice

President, Research and Development, and in 2012 I was promoted to my current position. I currently report directly to Meridian's CEO and am responsible for corporate-wide leadership of Meridian's research and development.

4. Among other duties, I oversee Meridian's research and innovation projects, as well as development of in-vitro diagnostic products (often referred to as "IVD" products), including strategies, policies, FDA compliance as it relates to new product development, and design control, clinical trials, valuation and protection of intellectual property, etc. I have direct involvement in Meridian's development of molecular diagnostic products and assessment of other companies' products, services, and intellectual property. Through my work, I have gained substantial personal knowledge of both Meridian's and other companies' products.

5. From 2006 to 2008, I was employed by EraGen Biosciences as a Vice President, Research and Development. EraGen Biosciences was acquired by Luminex Inc. in the third quarter of 2011. EraGen developed and commercialized molecular diagnostic products and drug discovery molecular tests. At EraGen, I was responsible for the full scope of research and development within the company, including product development, validation and verification testing, commercialization of Eragen's products and the development and protection of the company's intellectual property.

6. Prior to my work at EraGen, I worked from 2004 to 2006 as a Vice President, Research and Development, at Third Wave Technologies (which was acquired by Hologic Inc. in 2008). Third Wave operated in two distinct segments: Life Science (or research applications) and Molecular Diagnostics (or IVD products). My role involved guiding research, product support, quality control, regulatory submissions, and other technical operations.

7. In 2000 to 2003, I worked for Visible Genetics (which was acquired by Bayer Diagnostics in 2002). My title was Senior Scientist/Manager, Research and Development. I managed a group of scientists in the research and development department, developing new IVD products. I also served as a Manager for Clinical Laboratory Operations at Visible

Genetics, which involved managing clinical laboratory operations carried out by the company in accordance with CLIA[1] and FDA standards.

8. Through over a decade and a half of personal experience in the clinical diagnostics industry, including in research, product development, regulatory work, and management, I have come to know the industry very well. I have personal knowledge of the types of clinical diagnostics products that have been available in the market historically, their scientific bases, their functions, and the regulations that apply to them.

The Goods And Services Recitations in Meridian's and Illumina's Trademark Applications Describe Different Products and Services Marketed to Different Consumers.

9. I have reviewed the goods and services recitations in Meridian's registrations and applications for its ILLUMIGENE mark, Registration No. 3868081; ILLUMIGENE design & mark, Registration No. 3887164; ILLUMIPRO mark, Serial No. 77/768176, and ILLUMIPRO-10 mark, Serial No. 77/775316. I have also reviewed the goods and services recitations in the registrations owned by Illumina for its ILLUMINA mark, specifically Registration Nos. 2471539, 2632507, and 2756703. The recitations of goods and services in Meridian's and Illumina's applications and registrations are technically complex, and the nature of the products and services described therein cannot be understood by someone who does not possess the requisite scientific background. My education and experience, described above, allow me to interpret the scientific and technological terms and to understand the concepts being described.

10. Moreover, to someone with skill in these scientific fields, Illumina's recitations of products and services are extremely vague, and understanding their meaning requires knowledge about Illumina's actual activity in the marketplace and product offerings as context. I will discuss this in more detail below.

[1] "CLIA" stands for the Clinical Laboratory Improvement Amendments issued by the Centers for Medicare & Medicaid Services, which regulate all laboratory testing, except research, performed on humans in the United States.

The Recitations Of Goods And Services In Meridian's Applications

11. Meridian's recitation of goods is the same for its ILLUMIGENE and its ILLUMIGENE MOLECULAR SIMPLIFIED & design registrations, specifically: "Diagnostic kits consisting of molecular assays for use in disease testing and treatment of gastrointestinal, viral, urinary, respiratory and infectious diseases." One with applicable scientific education and/or experience would understand this recitation to describe IVD products because the goods described are "*diagnostic kits*" that are to be used in "testing *and treatment.*" Moreover, the term "molecular assays" in this context would be interpreted by one with skill in the field to mean an amplification/detection test for microbial, viral, or other disease-causing agents.

12. Meridian's recitation of goods is the same for its ILLUMIPRO and ILLUMIPRO-10 applications, specifically: "Diagnostic machine, namely, a stand alone closed heater and turbidity meter to be used for the amplification and detection of a closed tube molecular assay." One with applicable scientific education and/or experience would understand this recitation to describe machines to read IVD products because it discusses a "*diagnostic machine*" used in "a closed tube molecular assay" for "amplification and detection." To one skilled in the field, these words mean that the tests being run are used for detection of disease in patients (as opposed to analysis for research). The "amplification and detection" in such an assay keys one with the requisite knowledge to know this.

The Contrasting Recitations Of Goods And Services In The ILLUMINA Applications

13. To someone with applicable scientific education and/or experience, Illumina's recitations of goods and services in its ILLUMINA trademark registrations provide a stark contrast to Meridian's recitations of goods, indicating that the goods and services at issue are in a different field of medical endeavor from Meridian's with different interested consumers.

14. The recitation of services for ILLUMINA, Registration No. 2471539, is "Developing, to the order and specification of others, biological and/or chemical sensing systems which use random array technology to identify inorganic and organic molecules,

compounds and substances." One of skill in the field would understand immediately that Illumina is describing the development of complex, custom made equipment "to the order and specification of others" and using "random array technology." He or she would recognize that nothing in Meridian's trademark registrations and applications refers to any good or service that would use "random array technology." The definition of "random array technology" is vague and requires additional explanation. My understanding is that the term "random" implies that a system has random access for a sample input, and "array" means microarray technology. In other words, it is a system that utilizes random access sample inputs and uses microarray technology for analysis of organic and inorganic compounds. "Microarray" means that a system can analyze several biological markers (proteins, DNA molecules, RNA molecules) from a single sample or multiple samples in a single format. This technology is completely different from the ILLUMIGENE technology which utilizes a single analyte amplification and detection by turbidimetry. Simply put, Meridian does not use microarray technology generally, nor does it specifically use microarray technology in the ILLUMIGENE and ILLUMIPRO products. Moreover, ILLUMINA-branded products are in a different field of endeavor with different consumers - consumers who are looking not for "ready-made" IVD tests and locked IVD software on readers of those tests, but rather for open-platform research equipment that customers can tweak – certainly RUO products, not IVD products. The "random array technology" described in this recitation implies such open-platform research equipment that is used by consumers separate and distinct from the ready-made "kits" identified in Meridian's ILLUMIGENE recitations.

15. There are two more ILLUMINA registrations, with three additional recitations of goods and services. The goods description found in Registration No. 2756703 reads: "Scientific equipment and instruments, namely scanners, hybridization stations and fluidics delivery and computer systems sold as a unit and cassettes containing molecular sensing optical fiber bundles for analyzing cells, proteins, nucleic acids and other molecules of 50 to

10,000 daltons, sequencing dna, genotype, gene expression profiling and high through-put screening." The services description found in Registration No. 2632507 reads: "Scientific and medical research, namely, analysis of cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing dna, genotyping, gene expression profiling and high through-put screening."; and the goods description reads: "Chemicals, namely reagents for scientific or medical research use for analyzing cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing dna, genotyping, gene expression profiling and high through-put screening."

16. All of these additional recitations tell one with education and experience in the field that the products being discussed are RUO, not IVD, products, and are not similar to the products described in Meridian's recitations. The first recitation describes types of equipment that are used in scientific research, and "cassettes" specifically including "molecular sensing optical fiber bundles." To someone with the applicable scientific knowledge, this type of "molecular sensing" using "optical fiber bundles" stands in a stark contrast to Meridian's "molecular assays" using "heat" and "turbidity." Illumina's recited products are scientific equipment and specifically for "analyzing" the biological material at issue in a multiplex scale by employing "optical fiber bundles" – that is, specifically identifying and characterizing it -- not amplification and detection of a single analyte with the "heat" and "turbidity" approach utilized by Meridian's goods. These different approaches, in and of themselves, imply different consumers who are using the respective goods for different purposes. The two types of tests have critically different functions and contexts, with different applications and consumers: those who would be interested in a single target detection in a closed system for human in vitro diagnostics testing (Meridian's ILLUMIGENE product) on the one hand versus those seeking to identify multiple analytes in a high throughput screening context (Illumina's "sequencing dna, genotyping, gene expression profiling and high through-put screening" products, for instance). For example, an individual using an Illumina product for "high through-put screening" is not attempting to identify

a single pathogen in a human sample. Rather, that individual is conducting research on a large scale attempting to identify a number of different genetic variations that might be present in a person's DNA.

17. Similarly, the recitations of goods and services in Registration No. 2632507 are quite clearly RUO products and services, when read by someone with applicable scientific education and/or experience. They are specifically limited to "research use" and "scientific and medical research." There is no "diagnostic" or "clinical" utility expressed in Registration No. 2632507 at all. Other than that, when read by someone with skill in the field, these recitations are extremely vague, such that one would need to know more about Illumina's actual activities to understand what particular products and services are implicated.

Illumina's Actual Activity In The Marketplace In 2000 To 2009 Helps Someone With The Requisite Scientific Knowledge To Understand Its Vague Recitations of Goods And Services

18. Considering Illumina's actual activity in the marketplace at the time of these applications and the first uses claimed in their registrations (2000-2003), and up through the 2008-2009 timeframe, one with the applicable scientific background would understand that these recitations describe the detailed study and characterization of human genetic material in scientific research. Again, the consumers interested in such goods and services are dramatically different from the consumers who are interested in clinical diagnostic tests to detect infectious disease – that is, Meridian's ILLUMIGENE products.

19. I have reviewed the deposition testimony of Karen Possemato, Illumina's current Chief of Staff, and it serves to confirm my understanding, discussed above, that Illumina's recitations of products and services are technically complex and vague. Ms. Possemato testified that she worked in marketing for Illumina from 2004 to 2013. In 2007 to 2010, she was director of corporate marketing, and from 2010 to August 2013, she was senior director of corporate marketing. She has a bachelors degree in biochemistry. (Possemato Deposition, at 9, 17-18)

20. When Ms. Possemato was asked about the language in the first filed recitation of goods and services for the ILLUMINA mark, quoted in paragraph 14 above, she testified that the description did not mean anything to her and she did not know if Illumina ever provided the recited services. (Possemato Deposition, at 54-55)

21. When Ms. Possemato was asked about the language of the three other recitations of goods and services in Illumina's two other registrations for the ILLUMINA mark, quoted in paragraph 15 above, she was not able to comment on "the '50 to 10,000 daltons thing," a phrase that appears in Registration Nos. 2632507 and 2756703. She was not sure what "reagents" were being referred to in the product recitation, but generally testified that Illumina's reagents are sold to be used on the technological platforms that Illumina provides. She testified that Illumina's recited services are "genotyping and sequencing services," in which human (including prenatal) genetic samples are sent away to Illumina's laboratories to be tested, and Illumina sends back a report, along with consultation over the phone and provision of data. She also testified that Illumina's recited scientific equipment and instruments are components and systems whose only use is to do microarray analysis, and that Illumina is "obsoleting" all of the recited equipment and instruments such that they "are not available today." (Possemato Deposition, at 55-69, 73). Ms. Possemato's statement about scientific equipment and instruments used to conduct microarray analysis fits very well with my understanding of Illumina's Registration No. 2471539 which describes a "random array technology" instrument that utilizes microarray technology.

22. Accordingly, although Ms. Possemato did not describe the limitation of "50 to 10,000 daltons" in each of three recitations, she could confirm, by comparing the recitations to Illumina's actual products, that the recitations described reagents sold for use on Illumina's platforms; specific human genetic services offered through laboratories in consultation with the professionals who ordered the services; and discontinued systems that Illumina previously sold to support microarray analysis.

23. After Ms. Possemato's testimony, and applying my scientific education and experience to what she said about Illumina's goods and services recitations, it is even more evident that the recitations found in the ILLUMINA registrations are very different from the recitations associated with Meridian's marks, and that they relate to a very different market of consumers.

24. All of the ILLUMINA goods and services recitations, in light of Ms. Possemato's testimony and my scientific understanding, specify that the goods and services will be used in scientific research, human genetic sequencing or genotyping, and specifically by using microarray assays. None of Meridian's recitations relate to products that would serve those uses. Meridian's recitations discuss FDA-cleared "diagnostic kits" and FDA- cleared diagnostic machines using a turbidity meter on a closed-tube molecular assay; someone with the applicable education and/or experience would read Meridian's recitations to have absolutely nothing to do with scientific research, human genetic sequencing or genotyping, or microarray assays.

25. The consumers of such FDA- cleared "diagnostic kits" and "diagnostic machines" (that is, the products in Meridian's product recitations) are not the same as consumers of scientific research, human genetic sequencing or genotyping, and equipment for microarray assays (that is, the products and services in the ILLUMINA recitations). The consumers of "diagnostic kits" and "diagnostic machines" are treating/clinical physicians looking for an inexpensive and quick way to confirm or deny the presence of a particular bacteria, fungus, or virus. That is, they are asking the question, "Does this patient have the disease X?" The consumers of scientific research, human genetic sequencing or genotyping, and equipment for microarray assays are answering very different kinds of questions, and ones that are much more open-ended. For example, they are asking the question, "Do these 100 patients that present with cancer have the same type of cancer that derives from the same specific genetic sequence or are multiple genetic sequences responsible for the same type of cancer?"

Illumina's and Meridian's Products Are Different And Serve Different Consumers' Needs.

26. The disparity between the goods and services recitations in Meridian's applications and the ILLUMINA mark applications is not a coincidence. Considering the state of the companies and marketplace at the relevant time, along with my applicable education and experience, it is clear the relevant consumers implied in the recitations are not remotely the same. It is not a coincidence – it is a logical consequence of the very significant differences between the companies and their products at the time the parties' respective trademarks were applied for and registered.

27. In 2008, Illumina's products had zero presence inside a Clinical Diagnostic or Microbiology Laboratory. For the purpose of clarification, the Diagnostic Laboratory is a laboratory that performs diagnostic tests (also referred to as "in vitro diagnostic" or "IVD tests") on samples taken from the human body, and used in a broad range of applications to aid the physician or caregiver in reaching decisions. In October of 2008, Meridian announced it was developing a next-generation, molecular test for *C. difficile* to supplement its existing portfolio of products directed to this market. Attached as Exhibit A is a copy of that press release, and the subsequent press release announcing FDA clearance for that product – the ILLUMIGENE product. In 2008 to 2009, Illumina's products and services were focused on research applications as "Research Use Only" ("RUO") products and were not cleared by the FDA for "In Vitro Diagnostic" use ("IVD"). These RUO products are used by academic laboratories, medical centers for research purposes, government research entities, large pharmaceutical companies who do substantial research, and research laboratories, *not* the clinical diagnostic laboratories. In general, Illumina operated in the research market segment, similar to other companies like Life Technologies, Luminex, and the Life Science Division of Roche. Clinical Diagnostic Laboratories use IVD products, and Illumina had no IVD products at the time.

28. In a small number of medical institutions, or in much larger and well-funded institutions, researchers in the research laboratory side do work that could be considered, in one

sense of the word, "diagnostic," but it is not through the use of IVD clinical diagnostic products such as Meridian's ILLUMIGENE products. Rather, in this small subset of laboratories, researchers create their own diagnostic assays from RUO parts and components or use RUO products to conduct medical research studies, such as biomarker discoveries for different human diseases (cancers, inherited diseases, etc). To develop these assays, such researchers may use Illumina's products, along with components from many other suppliers, but those researchers and the people working with them are not buying "ready-made" clinical diagnostic products – kits – such as Meridian's. They are buying life sciences components and then *building* in-house diagnostic assays themselves – these are called "Laboratory-Developed Tests" or "LDTs." These products are sometimes referred to as "home brews" because the individual laboratory creates them themselves from various components.

29. I have reviewed the deposition testimony of Illumina's employee Naomi O'Grady, who makes some relevant comments that I agree with on this particular topic. Ms. O'Grady, who works for Illumina in the field of marketing related to oncology, gave a statement in this case on behalf of Illumina. At her deposition, she acknowledged that when laboratories use Illumina's components or equipment to make LDTs for a diagnostic purpose, the output of the laboratory is a "test report" sent by the laboratory to the ordering physician with no involvement from Illumina. Illumina would not review the report, would have no control over the report's content, and would have no control over the report's branding. As Ms. O'Grady testified, "No, they would not control that branding." (O'Grady Deposition, at 92-94)

30. What Ms. O'Grady says about LDTs in this passage matches my knowledge of that market. And that is not just a coincidence – it is necessary due to the nature of the regulatory environment and the market. If a test is providing a diagnostic answer, it must either be cleared by the FDA or it must be conducted in a CLIA-certified laboratory. The CLIA-certified laboratory may use equipment and consumables that are labeled for RUO, but such use does not somehow convert those components into diagnostic kits – far from it. Rather, the diagnostic

product involved is the laboratory's own LDT which is built from non-IVD components, and the process of building the LDT and using the LDT must be carefully controlled under CLIA regulations. Otherwise, the individual pieces of equipment and consumables used with that equipment would need to be separately cleared by the FDA as IVD products. The only "diagnostic product or service" in this LDT environment, necessarily due to the regulations, is the test report from the laboratory, and it must be issued by the laboratory itself – not by the manufacturer of the components used to construct the LDT. That is why Illumina can have nothing to do with the test report – its components are not FDA-cleared as IVD products. The market is simply not the same for RUO life sciences components as it is for IVD clinical diagnostic tests.

31. One example of an RUO life science component Illumina sells is "DisplaceAce." (Illumina sells DisplaceAce because it acquired Epicentre Technologies Corporation, a research tool company that sells enzymes and other components for life science applications, in January of 2011). DisplaceAce is Epicentre's brand name for *Bacillus stearothermophilus* DNA Polymerase (Bst), an enzyme that has been known for more than 30 years. This enzyme is also available from other research tool companies that are selling RUO components – New England BioLabs for example. Meridian was using the "DisplaceAce" enzyme as part of its ILLUMIGENE IVD kit when the ILLUMIGENE product initially received its FDA clearance. In order to use "DisplaceAce" in that cleared product, Meridian applied strict manufacturing and quality control oversight of Epicentre, went through development of an extensive manufacturing validation process on its own, and then conducted clinical trial studies with over 1,000 human samples. When Illumina informed Meridian, post acquisition, that it would cut off Meridian's supply of DisplaceAce, Meridian easily replaced its source through another supplier of an equivalent recombinant Bst DNA Polymerase by re-validating manufacturing and quality control processes and conducting additional clinical trial with human samples to demonstrate substantial

equivalency of this enzyme. This level of quality, process, design, and manufacturing control exemplifies the differences between marketing an RUO versus an IVD product.

32. The differences in the RUO versus IVD markets is further emphasized by the testimony of Karen Possemato that during the time she was director of corporate marketing for Illumina (which includes the years 2008 to 2009), she did not consider Meridian to be a competitor. (Possemato Deposition, at 82-87) In fact, Ms. Possemato essentially testified that comparing Illumina's products to Meridian's products would be like comparing apples to oranges. (Possemato Deposition, at 82-89) Her explanatory testimony on this topic is somewhat complex technically, but I understand it due to my relevant education and experience, and can explain further.

33. In discussing another company, Luminex, Ms. Possemato testified that currently, she does not consider Luminex to be a competitor. She explained that the Luminex technology offers a level of multiplexing of 100 or 200, while the Illumina platforms offer a level of multiplexing on the level of 100,000. "Multiplexing" essentially refers to the number of analytes from the same sample that can be run by one machine at one time. Ms. Possemato testified that comparing the two companies' products would be comparing "apples and oranges" due to the drastic difference in their multiplexing capabilities, i.e., 100,000 on the one hand versus 100 or 200 on the other.

34. Meridian's ILLUMIGENE and ILLUMIPRO/ILLUMIPRO-10 are inexpensive kits and readers for kits that simply say whether a person has one particular infectious disease or not. It is therefore even more drastically different from Illumina's products – it has a multiplexing level of 1. Put differently, the ILLUMIGENE product has no multiplexing capability whatsoever. (Possemato Deposition, at 82-89)

35. Viewed in light of my education and experience, I agree with Ms. Possemato that Illumina's products are drastically different from Meridian's in this way, and consequently they are viewed very differently by customers. Indeed, if comparing the "level 100,000" to the "level

100" is akin to comparing "apples and oranges," then further comparing the "level 100,000" of Illumina's products to the "level 1" of Meridian's products would be akin to comparing "apples and bananas;" even more drastically different.

Even After the 2008-2009 Time Period, Illumina's Products and Meridian's Products Remained Very Distinct, With Very Different Consumers.

36. I understand that after the 2008-2009 time period, Illumina received FDA clearance for a few IVD products, namely the Veracode Genotyping Test for Factor V and Factor II using the BeadXPress system (the "Veracode Genotyping Test"). Later, in 2013, Illumina received FDA clearance for two cystic fibrosis gene sequencing assays called the MiSeqDx Cystic Fibrosis 139-Variant Assay, and the MiSeqDx Cystic Fibrosis Clinical Sequencing Assay. These products, too, are very different from Meridian's ILLUMIGENE products and the ILLUMIPRO readers.

37. The Veracode Genotyping Test and the BeadXPress system on which it ran have been discontinued by Illumina. During the short period of time when it was available, the test was based on nucleic acid amplification and solid-phase hybridization technology to detect single nucleotide polymorphisms (SNPs) that cause human inherited diseases (coagulation factors in that case), and it has nothing to do with infectious disease or microbiology laboratories. From a technical standpoint, users of the Veracode Genotyping Test were interested in identifying a human single nucleotide polymorphism (i.e. a genetic mutation thought to be responsible for a given disease state), not detection of infectious diseases through amplification in a closed tube molecular assay, as with ILLUMIGENE and ILLUMIPRO. The technology platforms are entirely separate, fundamentally different, and incompatible with one another. In essence, the Veracode technology was very similar to the xTAG technology that is developed and commercialized by Luminex Inc. and would have been marketed to the same consumer.

38. Meridian's ILLUMIGENE and ILLUMIPRO products are wholly unrelated to Illumina's Veracode Genotyping Test, and the two technologies cannot be used together or combined in any way. Illumina's BeadXPress instrument cannot be used with Meridian's ILLUMIGENE tests. Meridian's ILLUMIPRO machines cannot be used with Illumina's Veracode Genotyping Test or any of Illumina's other products. A lab technician who may be exposed to both companies' products (assuming this would occur), would be keenly aware of this incompatibility.

39. Because of the function and focus of the Veracode Genotyping Test, users of that test would work in Hematology or Human Genetics departments. This is in contrast to users of Meridian's ILLUMIGENE clinical diagnostics products, who would be in Infectious Disease, Virology, or Microbiology departments. Analyzing human genetics is a totally separate scientific field from detecting infectious diseases.

40. Illumina's only current IVD products are the MiSeqDx Cystic Fibrosis 139-Variant Assay and the MiSeqDx Cystic Fibrosis Clinical Sequencing Assay (the "MiSeqDx Cystic Fibrosis Assays." These assays are entirely separate and fundamentally different from Meridian's ILLUMIGENE products and its ILLUMIPRO readers and serve very different markets. The MiSeqDx Cystic Fibrosis Assays are based on a next-generation sequencing platform that allows users to perform simultaneous analysis of more than 100 genetic mutations in a single test. The consumer of such a product is analyzing what causes human inherited diseases (cystic fibrosis in this case), and it has nothing to do with the analysis that is conducted in infectious disease or microbiology laboratories where the technician is trying to perform a specific test quickly in order to identify what is making a patient sick so that he can be treated. From a technical standpoint, users of a MiSeqDx Cystic Fibrosis Assays are interested in identifying a set of human single nucleotide polymorphisms (i.e. genetic mutations thought to be responsible for a given disease state), not detection of infectious diseases through amplification in a closed tube molecular assay, as with ILLUMIGENE and ILLUMIPRO.

41. Meridian's ILLUMIGENE and ILLUMIPRO products are wholly unrelated to Illumina's MiSeqDx Cystic Fibrosis Assays, and the two technologies cannot be used together or combined in any way. The MiSeqDx Cystic Fibrosis Assays run on a MiSeq instrument cannot be used with Meridian's ILLUMIGENE tests. Meridian's ILLUMIPRO machines cannot be used with the MiSeqDx Cystic Fibrosis Assays or any of Illumina's other products. A lab technician who may be exposed to both companies' products (assuming this would occur), would be keenly aware of this incompatibility.

42. Because of the function and focus of the MiSeqDx Cystic Fibrosis Assays, users of that test would work in the Genetics Counseling or Human Genetics departments. This is in contrast to users of Meridian's ILLUMIGENE clinical diagnostics products, who would work in Infectious Diseases, Virology, or Microbiology departments. As stated above, analyzing human genetics is a totally separate field from detecting infectious diseases.

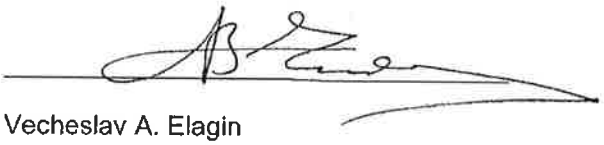
43. And in any event, Illumina's 510(k) clearances for the above-described products occurred between 2010 and 2013. In the 2008 to 2009 time period, an Illumina FDA-cleared product simply did not exist.

44. Even after those Illumina products were cleared by the FDA, the clinical diagnostic community did not consider Illumina or its products to be competitive with Meridian and its products. For example, attached as Exhibit B is a copy of a slide presentation given by Dr. Stephen Young, Professor in the Department of Pathology of the University of New Mexico. This presentation was given to prospective consumers at a Meridian-sponsored workshop at the Association for Molecular Pathology Annual Meeting which ran from 17-20 November 2010 in San Jose, California. I attended this presentation and introduced Dr. Young. In this presentation, Dr. Young discussed the various solutions available to someone performing molecular assays in the microbiology laboratory – Meridian's target market. Along with Meridian's ILLUMIGENE product, four other companies were discussed as offering competitive products: Cepheid, BD, Nanosphere, and IQuum. Illumina was not discussed in this

comparative analysis because Illumina did not at the time (and does not now) offer a competitive product.

Pursuant to 37 C.F.R. § 2.20, the undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting therefrom, declares that all statements made of my own knowledge are true; and all statements made on information and belief are believed to be true.

Executed on February 5, 2015.



Vecheslav A. Elagin

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing **OPPOSER'S TESTIMONY** has been served on Applicant's attorney of record by sending one copy on April 6, 2015 via first-class mail to:

J Michael Hurst
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Sarah Beno Couvillion